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An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour

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An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour

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Abstract

An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour

Evidence-based prescribing is promoted in national policy and is an essential component of good quality, effective and safe healthcare. Promotion of evidence-based prescribing is fundamental to the pharmacist prescribing advisor's professional role in primary care.

The aim of this study was to evaluate the impact of an intervention delivered by pharmacist prescribing advisers on GP prescribing. The intervention involved promotion of evidence-based prescribing utilising several approaches, which are known to be successful in influencing professional behaviour. Management of Type 2 diabetes and use of non-steroidal anti-inflammatory drugs were clinical areas targeted within the intervention.

The study was designed and powered through quantitative methods to determine, the impact of the intervention on prescribing outcomes as measured using ePACT prescribing data. The impact on measurable patient-orientated outcomes was also assessed.

The qualitative evaluation explored GP perceptions, attitudes and beliefs regarding evidence-based medicine and considered the impact of the intervention from the GP perspective through semi-structured interviews.

The results provide clear evidence for the impact of primary care pharmacists in influencing GP prescribing behaviour. Statistically significant differences in achievement of primary prescribing outcome measures aimed at improving uptake of evidence-based prescribing (including reduction in diclofenac prescribing, $p<0.05$) were demonstrated in the intervention group compared with control.

Statistically significant differences in patient-oriented outcomes were also demonstrated (HbA1c target ≤7.5%, $p<0.01$). This finding challenges a main criticism of evidence-based medicine in that evidence is lacking to demonstrate that incorporation of evidence-based research into clinical decision-making improves outcomes for patients.

Both qualitative and quantitative evaluations indicated that GPs had internalised and incorporated key evidence-based messages into their clinical decision-making as promoted and supported by the pharmacists.

The intervention was shown to be effective in promotion and implementation of evidence-based prescribing in practice and provides an indication of how primary care pharmacists might develop their future role.

List of Abbreviations

ACCORD	Action to Control Cardiovascular Risk in Diabetes
ACE-I	ACE-Inhibitor
ADQ	Average Daily Quantity
ADVANCE	Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation
A-II-I	Angiotensin Receptor Antagonist
APM	Annual Prescribing Meeting
ARB	Angiotensin Receptor Blocker
ASTRO-PU	Age-Sex and Temporary Residence Originated Prescribing Unit
BNF	British National Formulary
BMJ	British Medical Journal
BP	Blood Pressure
CARDs	Collaborative Atorvastatin Diabetes Study
CI	Chief Investigator
CME	Continuing Medical Education
CKD	Chronic Kidney Disease
COX	Cyclo-Oxygenase
COX-I	Cyclo-Oxygenase-Inhibitor
DTB	Drug and Therapeutics Bulletin
EBOR	Evidence-based OutReach
EBM	Evidence Based Medicine
EBP	Evidence Based Practice
eCAB	electronic Current Awareness Bulletin
EOV	Educational Outreach Visit
ePACT	electronic Prescribing Analysis and CosT
EPOC	Effective Practice and Organisation of Care
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HbA1c	Haemoglobin A1c
HPS	Heart Protection Study
HCP	Health Care Professional
MI	Myocardial Infarction
MHRA	Medicines and Health Research Authority
MMF	Medicines Management Function
MMT	Medicines Management Team
MRC	Medical Research Council
NAO	National Audit Office
NatPaCT	National and Primary Care Trust Development Programme
NeLM	National electronic Library of Medicines
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPC	National Prescribing Centre

NRES	National Research Ethics Service
NSAID	Non-Steroidal Anti-Inflammatory Drug
NYDTC	Northern and Yorkshire Regional Drug and Therapeutic Centre
OA	Osteoarthritis
PBC	Practice Based Commissioning
PCO	Primary Care Organisation
PCT	Primary Care Trust
POPADAD	Prevention of Progression of Arterial Disease and Diabetes
PPI	Proton Pump Inhibitor
RA	Rheumatoid Arthritis
RAS	Renin-Angiotensin System
RaPP	Rational Prescribing in Primary Care
RCGP	Royal College of General Practitioners
RCT	Randomised Controlled Trial
RPSGB	Royal Pharmaceutical Society of Great Britain
SSRI	Selective Serotonin Reuptake Inhibitor
STAR-PU	Specific Therapeutic group Age-sex Related Prescribing Units
SIGN	Scottish Intercollegiate Network
SMBG	Self-Monitoring of Blood Glucose
SORT	Strength of Recommendation Taxonomy
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
UKPDS	United Kingdom Prospective Diabetes Study
VADT	Veterans Affairs Diabetes Trial

Chapter 1

Introduction

Provision of prescribed medication for patients is fundamental to the management of many acute and chronic conditions. The most common healthcare intervention in the NHS is issue of a prescription. Evidence based prescribing is promoted in national policy and is essential in providing good quality, effective and safe healthcare to patients.[1,2,3]

Promotion of evidence-based prescribing is fundamental to the pharmacist prescribing advisor's professional role in primary care. However, prescribing decisions are often encountered in practice, which are contrary to current best evidence. Inappropriate prescribing and lack of an evidence-based approach may not only result in ineffective treatment but may also be associated with potentially serious safety related issues.

There are a number of external influences which clearly have an impact on general practitioner (GP) prescribing decisions including the pharmaceutical industry, requests from specialists, pressure from peers and not least, patients themselves.[4] Such influences do not necessarily represent an evidence-based perspective and may in fact contradict the available evidence or prescribing recommendations. Questions therefore arise around what does influence prescribing choices and why clinicians make the choices they do particularly in the light of available evidence to inform clinical decision-making in practice.

The absence of a sound clinical evidence base underpinning many clinical decisions is widely suggested.[5] However, compared with some other areas of clinical practice, evidence from large well designed randomised controlled trials of medicines in study populations have repeatedly demonstrated that those who receive evidence-based therapies have better outcomes than those who do not.[6,7] Despite the availability of high quality research from large well-designed trials however, incorporation of evidence into the decision-making process and translation into routine practice remains an important goal.[8]

Despite initiatives to promote evidence-based prescribing, evidence is also lacking to demonstrate that incorporation of evidence-based information into prescribing decisions improves patient care or patient outcomes.[8] Additionally, prescribing patterns of many GPs indicate that they do not embrace the principles of evidence-based practice. Certain prescribing decisions may be considered irrational at best, potentially dangerous at worst.

Medicines Management Services in NHS Primary Care Trusts (PCTs) fulfil widespread roles influencing decision-making processes and affecting provision of medicines related services across primary, secondary and tertiary care.[9,10] A key principle embraced is promotion of evidence-based prescribing, influencing GP prescribers and extending initiatives across the primary/secondary care interface.

Typically, Medicines Management functions include provision of prescribing support at practice and organisational level, as well as working across primary, secondary and tertiary care interfaces.[10] Pharmacists are the key professionals involved in developing and achieving prescribing initiatives.[9] In order to facilitate prescribing change, Medicines Management activities often involve GP practice visits, audit and provision of prescribing feedback as well as provision of synthesised evidence-

based information often disseminated as guidelines, newsletters and PCT policies. Organisational level activities include facilitation and involvement in local therapeutic networks, primary/secondary care decision-making committees and educational initiatives for local healthcare professionals.

Approaches adopted by pharmacists for influencing prescribing are often multifaceted and may be employed with varying success. They may involve activities identified above and incorporate specific strategies to promote uptake of evidence-based medicine in prescribing.[11] Although not strictly defined as a strategy, the resulting approach may be considered as integration of known successful approaches with social influence strategies for promoting evidence based medicine in prescribing. This approach however has not been tested.

Various interventions have been shown to be effective in changing professional behavior although evidence is inconclusive. Interventions which are targeted at changing behaviour are defined as complex interventions, in other words comprising a number of separate elements consisting of a number of interacting components. Evaluation of complex interventions is by definition difficult because of problems of developing, identifying, documenting and reproducing the intervention. In order to evaluate a complex intervention it is therefore necessary to define as clearly as possible each element of the intervention and standardise delivery of it in practice.

Some of the methods known to be successful in influencing professional behaviour are utilised by prescribing advisers as part of their role in influencing prescribing change. However, there is no clearly defined approach (for which the component parts are described) adopted for promotion and implementation of evidence-based prescribing in practice, and there is currently little evidence that such an approach, if adopted, works.

The purpose of this research is to define, implement and evaluate an intervention delivered by pharmacist prescribing advisers in primary care, which is intended to influence GP prescribing behaviour. The intervention which is by nature complex, will incorporate approaches which are known to be successful in influencing professional behaviour. It is intended to demonstrate that the defined evidence-based intervention works by changing GP prescribing behaviour.

The study seeks to establish, through a mixed methods approach whether suitably skilled primary care pharmacists can promote the uptake of evidence-based prescribing by general practitioners. The research seeks to provide quantitative evidence to demonstrate that the intervention improves prescribing by demonstrating changes in GP prescribing patterns. It also seeks to establish whether improved outcomes which matter to patients can be demonstrated.

Qualitative methodologies are also employed in order to explore concepts of incorporation of evidence into the clinical decision-making process by professionals in practice. They seek to provide further evidence in order to gain greater understanding regarding the processes of internalisation of evidence-based medicine into decision-making by clinicians and by contributing to knowledge in an area which is little understood.

This study is exploratory in nature and aims to ensure thorough development of the intervention in order to establish its application as intended in practice. It is hoped that the results obtained may inform future medicines management strategies for influencing prescribing behaviour, and ultimately provide the basis for further research.

Chapter 2

Literature Review

2.1 Introduction

The initial part of the literature review describes the principles and development of Evidence Based Medicine and its application in practice. It explores how clinicians make clinical decisions and obtain information to inform those decisions. It describes means of getting research evidence into practice and identifies barriers to the uptake of research evidence into the clinical decision-making process. The particular importance of evidence-based prescribing is also considered here.

Translation of evidence into practice and incorporation into the process of making prescribing decisions is fundamental to the prescribing adviser role in influencing GP prescribing behaviour. The literature review therefore explores the evidence for interventions which are known to promote behaviour change in practice, in particular, academic detailing which is the method underpinning the intervention in this study. It summarises the evidence for approaches that are known to work and what does not work in influencing behaviour change. The evidence for the impact of pharmacists on influencing prescribing behaviour is then specifically explored as part of the review.

The systematic literature search methodology is summarised in Appendix 1.

2.1.1 Prescribing Advisers in Primary Care

Pharmacists are the key professionals employed in influencing prescribing in primary care and are fundamental to this project in terms of their role in delivering the intervention which is to be evaluated. This chapter therefore describes the basis of the role, functions and skills of the pharmacist prescribing adviser, set within the context of the Medicines Management function in primary care and identifies the approaches typically adopted in supporting GPs in prescribing objectives. It also summarises the provision and availability of clinical and professional support for the primary care pharmacist role in practice.

2.1.2 Theoretical Basis of Study Evaluation

The evaluation of any intervention intended to change behaviour is by nature complex. This study is based on the evaluation of a complex intervention. This section describes the characteristics of complex interventions and highlights the difficulties which may be encountered in evaluating complex interventions. It also summarises the principles which should be considered when developing and evaluating a complex intervention, in particular, clear definition of its component parts and standardisation of approach.

2.2 Evidence Based Medicine

The underlying philosophy of evidence-based medicine (EBM), was first described in 1992 as representing a new paradigm and new approach in the teaching and practice of medicine. It de-emphasised intuition, unsystematic clinical experience and pathophysiological rationale as sufficient basis for clinical decision-making. Instead, it favoured new skills (of question formulation, search and retrieval of the best available evidence, and critical appraisal of studies to ascertain validity of results) which practitioners need in accessing, appraising and applying best available evidence for incorporation into the decision-making process.

Traditionally, the focus of teaching and the practice of EBM was based on training individuals how to seek answers to questions themselves by following a five step model. (Table 2.1)[5,12,13,14]

The five steps involved in practicing evidence based medicine
1. To convert information needs into an answerable question 2. Access, with maximum efficacy, current best evidence to answer the question 3. Critically appraise the evidence 4. Integrate critical appraisal with clinical expertise and patient factors 5. Evaluate effectiveness and efficiency

Table 2.1 The Traditional Five Step Model Approach to the Practice of Evidence Based Medicine

It was recognised that in order to practice and incorporate EBM into clinical decision-making processes, clinicians would need to develop and apply skills in accessing most relevant and up to date evidence-based information.[12,13,15] This assumption however relies on the fact that the individual will adopt the approach in order to seek appropriate answers and depends on the individual being able to determine relevant clinical questions in practice. One study exploring questioning behaviour in GPs concluded that doctors would need to become more questioning in their routine practice if EBM and associated self-directed learning were to be successful.[13,16]

A large number of publications on the subject of evidence-based practice are available in the literature. Many texts intended to guide practitioners, particularly doctors, in how to develop and apply skills in developing answerable clinical questions, accessing the current best evidence, critically appraising the evidence and getting research into practice also exist.[5,14]

The most widely used definition of Evidence Based Medicine is probably that expressed by Sackett and colleagues in 1996.[17]

“Evidence Based Medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available evidence from systematic research.”

Much has been published on the benefits of EBM and discussions have stimulated both positive and negative reaction from clinicians and academics.
EBM has been described as promoting 'Cookbook' medicine, a term used to describe the practice of medicine by strict adherence to practice guidelines and which may not be an appropriate substitute for clinical judgement. EBM has also been depicted as denigrating clinical expertise and ignoring patient values.[18] Critics also argued that application of evidence from randomised controlled trials (RCTs), which form the basis of EBM as well as many guidelines, is not necessarily generalisable to the general population, and may potentially lessen the focus from patient-centred medicine.[19] These misperceptions may have arisen initially because of a failure to appreciate step four in the five-step model described previously.[8]

Criticisms regarding the limitations of EBM were summarised along with commonly held misperceptions concerning EBM in a commentary published in 2000 and are summarised in Table 2.2.[20]

Limitations:

Universal to the practice of medicine

- Shortage of coherent, consistent and relevant scientific evidence
- Difficulties in applying the evidence to individual patients
- Barriers to the practice of high-quality medicine (e.g lack of resources, costs)

Unique to the practice of evidence-based medicine

- Requirement to develop new skills in finding and accessing the evidence
- Limited time and resources to seek out information
- Paucity of evidence that EBM 'works'

Misperceptions:

- Evidence-based medicine denigrates clinical expertise
- It ignores patient values and preferences
- It promotes a 'cookbook' approach to medicine
- It is a cost-cutting tool
- EBM is an ivory tower concept
- It is limited to clinical research
- It leads to therapeutic nihilism in the absence of evidence for randomised controlled trials

Table 2.2 Commonly cited limitations and misperceptions of evidence-based medicine (Adapted from 'Occasional Essay' Straus and McAlister, 2000)

Early in the EBM movement, it's proponents sought to allay perceived misinterpretations that practicing EBM may ignore certain aspects of more traditional medicine such as clinical training, clinical experience, intuition and clinical problem solving.[17] They challenged the view that EBM is 'cookbook' medicine and indicated that doctors need to use both clinical expertise and the best available external evidence and that neither alone is enough.

The concepts of EBM have continued to evolve as criticisms and limitations of earlier models were addressed. The emphasis being that research evidence alone is not adequate to guide action and that clinicians must apply their expertise to assess the patient and incorporate patient preferences or values before making a management recommendation.[18,21]

EBM involves the active incorporation of relevant evidence into the clinical decision-making process, and is therefore regarded as integration of best research evidence with clinical expertise and patient values.[5,13]

In 2004, a series of articles in the BMJ sought to reflect on the challenges of practicing and teaching EBM, highlighting the work that had been done in the field and providing an opportunity to point the way forward. It was noted that as an intervention, not only had EBM been difficult to define, but it was also difficult to evaluate. It pointed out that whilst changes in knowledge and skills are relatively easy to detect, changes in attitudes and behaviours were harder to confirm, with changes in patient outcomes being even more challenging to detect.[22,23]

A number of themes emerged from the articles. Research had demonstrated that educational interventions involving EBM had improved knowledge, skills and self-reported behaviours. EBM was being incorporated more widely into learning environments with the principles of EBM becoming core concepts.[8,24] One systematic review of educational interventions concluded that whilst critical appraisal and EBM skills can be taught through standalone courses, improvements in skills, attitudes and behaviour are more effective when taught in clinical practice.[24]

Important developments in EBM included improved access to evidence through availability and popularity of structured abstracts and secondary journals summarising studies of high relevance and methodological quality. The availability and accessibility of regularly updated evidence based information from credible sources such as the Cochrane Library with its systematic reviews and BMJ 'Clinical Evidence' were cases in point.

The importance of and ongoing requirement to produce evidence from high quality research to inform clinical practice remained. However, because of the sheer volume of published information available requiring review and evaluation, knowledge translation was highlighted as a major challenge to ensure that clinicians have access to relevant and current best evidence.[25]

2.2.1 Hierarchy of Evidence

Different research study designs carry different 'weight' in terms of the reliability of the evidence obtained and there is broad agreement on the relative strength of the main types of research in the 'hierarchy of evidence' which is fundamental to the practice of EBM. Well conducted prospective double-blind randomised controlled trials are regarded as 'gold standard' although systematic reviews or meta-analyses of RCTs are placed higher in some hierarchies. Non-blinded studies are more reliable than retrospective studies. Observational studies followed by expert opinion and clinical experience are ranked lowest.[14,26,27,28]

Recommendations from different guidelines however, may differ or even disagree despite citing the same studies. One study demonstrated that less than a third of recommendations based on evidence from RCTs were actually based on high quality evidence, indicating that guideline recommendations should not necessarily be assumed to provide high quality evidence for therapy recommendations.[29]

A number of grading schemes have been developed to assess the quality and hence the strength of evidence from primary research (e.g. SORT, GRADE). Levels of evidence may therefore be allocated to published research findings or guidelines to help clinicians determine the quality of evidence in order to facilitate incorporation of EBM into their clinical decisions.[30]

2.2.2 Progress in Evidence Based Medicine

Understanding of and implementation of EBM in practice has come a long way since its inception and few would argue that the principles of EBM be rejected. It is widely accepted that considerable progress has been made.[25,31]

The term Evidence Based Practice (EBP) is now employed to encompass healthcare and healthcare professionals (HCPs) from all disciplines and is regarded as a key skill.[8,13,32] Teaching EBP has become an integral part of undergraduate and post-graduate curricula for many healthcare professionals.[8,13] The emphasis on EBP in many medical schools and training programmes is also shifting from development of skills in individual evidence appraisal towards focus on implementation of evidence in practice.[31]

Despite advances in EBM, a number of challenges still remain.[8] Provision of high quality evidence from clinical research is not alone sufficient to change behaviour. Knowledge translation and interventions which aim to address implementation of evidence in practice as well as having effective means of measuring effectiveness are all deemed necessary.[8,25]

2.2.3 Application of EBM in Practice

Despite availability of high quality evidence from large well-designed RCTs, and the evolution of evidence based medicine, medical research is constantly producing evidence-based findings which are not routinely incorporated into clinical decision-making or translated into healthcare practice.[33,34,35] Clinical practice in many instances appears at odds with even clear cut research results.[36,37]

There is currently no clear evidence which demonstrates that incorporation of evidence-based research into clinical decision-making improves outcomes for patients. Getting research into practice remains an important objective.

It has been suggested that the most basic assumptions of EBM remained unproven and largely untested. A key factor is lack of understanding of how the process of EBM is adopted and internalised by practitioners. It is not known whether convincing information leads to optimal decision-making or whether clinicians base their decisions on best evidence, or whether EBM ultimately affects patient care.[8,38] Evidence of improved patient outcomes remains lacking.

Moreover, many clinicians may not embrace the evidence-based paradigm or adopt the principles in practice. For research-based evidence to be incorporated into practice may still require HCPs to change long-held patterns of behaviour.[3,12,39]

2.2.4 Clinical Decision Making

One factor in considering the incorporation of EBM into practice is an understanding of what influences clinical decision-making. Despite a number of studies which have

sought to establish why clinicians fail to incorporate evidence into the clinical decision-making process, the reasons remain unclear.

One key ethnographic study explored how primary care clinicians derive individual and collective healthcare decisions. The authors concluded that:

'Clinicians rarely accessed and used explicit evidence from research or other sources directly, but relied on 'mindlines' - collectively re-enforced internalised tacit guidelines'. These were informed by brief reading but mainly by their own and colleagues' experience, their interactions with each other and with opinion leaders, patients and pharmaceutical representatives and other sources of largely tacit knowledge - resulting in socially constructed "knowledge in practice"'.[40]

Although in no way providing evidence for incorporation of EBM into practice, this study highlighted the potential for exploiting existing formal and informal networking as a key means of disseminating evidence to practitioners.

Coumou considered how primary care physicians seek answers to clinical questions in reaction to the increase of greater availability of online journals, bibliographic databases and the internet during 1992-2005 (which also corresponded with the evolution of EBM). He also concluded that despite the enormous increase and better accessibility of electronic information sources, primary care clinicians seek answers only to a limited number of questions about which they first consult colleagues and paper sources.[41]

Pharmaceutical representatives, hospital consultants, hospital prescribing and patients have all been shown in other studies to be primary influences on the uptake of new drugs by GPs.[4,42,43] One study concluded that 'GPs are largely reactive and opportunistic recipients of information, rarely actively searching information, influenced more by 'who says what'.[4] The patient, practitioner-patient relationship, verbal and non-verbal communication have also been identified at practitioner level as factors relevant to the decision-making process. Importantly, however, the available evidence suggests that evaluation and critical appraisal of the evidence are not key elements of the decision-making process.

Conclusions from these and other studies reinforce the concept of the 'mindline' model and its significance in how clinicians seek information to answer clinical questions in practice. They also highlight the challenge in that barriers to implementation of EBM remain.

2.2.5 Barriers to the Uptake of Translating Evidence into Practice

Scott suggests that it is necessary to understand better the determinants of clinician behaviour and a clinician's view of compelling evidence to improve evidence-uptake. Understanding of integration into the process of clinical decision-making is also necessary.[36] Barriers to and incentives for evidence uptake may also be mapped out at micro, (individual physician and patient), meso (social and organisational) and macro (economic and political) level. It may then be possible to devise suitable methods for optimising behaviour which can then be tested.[3,36]

Barriers towards evidence-based thinking and acting have been explored and reviewed in a number of qualitative studies.[43,44,45] One study explored barriers as perceived by GPs at micro, meso and macro level through grounded approach.[41] Themes identified by GPs themselves as barriers to implementation of evidence into practice in primary care include GP personal/professional experiences, patient-doctor relationship, perceived tensions between primary/secondary care, feelings about the evidence, logistical problems, competencies, time and EBM resources.[44,45] Some GPs regard clinical evidence as a square peg to fit in the round whole of the patient's life.[45]

In addition, physicians frequently feel overwhelmed with information. Although they may have a positive attitude towards EBM, they lack time and skills to appraise scientific papers and have difficulty finding, assessing, interpreting and applying current best evidence.[46,47] Many appear well aware of the gaps in their knowledge, their problem being, to get adequate information quickly.[48]

In order to practice EBM effectively, clinicians today cannot hope to obtain the information they need by searching and evaluating it themselves. Better transition of information making it focussed and accessible to them is required. Proposed solutions include services that abstract and synthesise information, and improving effectiveness of educational and quality improvement programmes for practitioners.[47]

2.2.6 Evidence Based Prescribing

Evidence-based prescribing is an essential component of good quality, effective and safe healthcare for patients which underpins national healthcare policy and guidance.[1,2,3]

Inappropriate prescribing and lack of evidence-based approach may result in ineffective treatment and serious safety related issues. Between 5-17% of hospital admissions in the elderly are known to be medication related.[1] Incorporation of evidence in prescribing decisions is therefore a key intervention in clinical decision-making.[1,2] It cannot be assumed however that dissemination of information or even awareness of evidence-based research leads to incorporation of knowledge into clinical decision-making or, that it will ultimately bring about a change in practice.

There is currently little evidence to demonstrate that incorporation of evidence into clinical decision-making improves outcomes for patients although results from robust randomised controlled trials has repeatedly demonstrated that those who do receive evidence based therapies have better outcomes than those who do not.[5,6,7]

Provision of evidence-based prescribing support from a reliable and trusted source using a combination of methods which are known to work in influencing behaviour change may be an effective approach to incorporation of the evidence base into clinical-decision making relating to prescribing. By understanding the barriers faced by clinicians, it is possible to develop a tailored approach intended to overcome the barriers and encourage change in behaviour.[3,49] This study seeks to address identified barriers by means of an intervention which will engage practitioners and promote integration of evidence-based prescribing into the clinical decision-making process.

The term 'evidence-based' often precedes many recommendations and guidelines which are not transparently linked to the underlying evidence base and which is not necessarily accessed from credible sources.[31] There are often commercial interests behind promotion of much information. Unsophisticated users of the medical literature may incorrectly assume that such reports are based on current best evidence and advocate implementation in practice.[31] There therefore remains a requirement for the promotion of EBM through access to and dissemination of robust evidence-based information. It is necessary that clinicians have access to appropriate sources of evidence, evidence summaries and guidelines that acknowledge the most current EBM thinking. Primary care pharmacists are in an ideal position not only to access the evidence but also communicate evidence-based prescribing information to other health care professionals.

2.2.7 Evaluation of Evidence-Based Practice

The EBM paradigm is multifaceted and complex in nature and despite the volume of published papers on the subject, demonstration of the success of the EBM movement is not straightforward. Clear evidence is lacking in relation to various domains of EBP including uptake by professionals, change in clinical behaviour and translation of evidence into practice and not least the impact on the healthcare of the patient.[8]

One systematic review designed to identify measures for assessing practice change in practitioners following an intervention aimed at increasing uptake of evidence into practice concluded that most studies measured the effect of the intervention at the level of the practitioner. Few actually measured whether any change in practice resulted in a change which affected patient health status. Most did not report validity or reliability of the measures used.[50]

Another systematic review of studies on tools designed to evaluate education in EBP indicated that most concentrated on EBP knowledge and critical appraisal skills rather than objectively documenting behaviours in actual practice. The authors concluded that further development and testing of instruments to test attitudes, behaviours and other aspects of EBP were necessary.[51]

More recently, a classification for standardising the components and development of EBP learning assessment tools which includes practitioner attitudes, values, behaviours and potential benefits to patients has been proposed,. However, the focus in practice remains evaluating skills in formulating and answering clinical questions rather than assessing attitudes and actual behaviours.[52]

2.3 Evidence for Interventions to Influence Behaviour Change in Practice

Many studies and reviews have sought to identify interventions which influence HCP behaviour and bring about change in practice.[35,39] Specific interventions, interventions targeted at improving specific behaviours (patient management, disease management, preventative care, prescribing, service utilisation) and broad strategies (guideline implementation, continuing medical education) have all been considered.

The NHS Centre for Reviews and Dissemination reported an overview of forty-four systematic reviews of different dissemination and implementation intervention approaches to changing professional practice.[39]

Specific interventions which have been shown to be consistently (but generally moderately) effective are interactive educational meetings, educational outreach visits (academic detailing), opinion leaders, patient mediated interventions and reminders/prompts issued during consultation.[39,53] Multifaceted interventions and those assessing potential barriers to change were more likely to be effective than single interventions. Multifaceted interventions tended to effect changes in performance but less consistently in health outcomes.

Review of interventions specifically intended to improve prescribing indicated that educational outreach approaches and ongoing feedback were generally effective. However, inadequately controlled reporting of some studies highlighted a need for rigorous evaluation of the dissemination and implementation strategies. Educational outreach was considered as potentially a promising approach for modifying professional behaviour, especially prescribing.

One systematic review of 235 studies specifically explored the effectiveness of guideline development, dissemination and implementation strategies. Single interventions included reminders, dissemination of educational materials and audit and feedback. Multifaceted interventions, (twenty-three involving educational outreach), were included in the review. The majority of interventions observed modest to moderate improvements in care.[54]

Results indicated that reminders are potentially effective, and that educational outreach may result in modest improvements in the process of care. The evidence for educational materials, audit and feedback and patient directed interventions was less robust as there were fewer interventions, nevertheless, these may result in modest or moderate effects.

The authors highlighted difficulties in interpretation of the results, arising as a result of differences in context, barriers and targeted behaviour in the studies assessed. Most studies used process measures for their primary endpoint, rather than measures of care and only three of the guidelines were explicitly evidence based. The overall quality of the studies was also described as poor. Some of the results were at odds with other reviews.[54] It was suggested however, that dissemination of educational materials and short educational meetings may be an appropriate circumstance in which to engage with practitioners. The conclusions overall were largely tentative, indicating that further well designed robust evaluations were required. They also seemingly emphasise recognised difficulties encountered in the evaluation of complex interventions.

Barriers to guideline adherence have been identified as lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy, lack of outcome expectancy, and inertia of previous practice.[55] Clinical decision support systems using prompts based on patient-specific characteristics may suggest potential for improving patient care.[56] However, computerised decision support systems intended to increase adherence to evidence-based guidelines have been shown to be ineffective.[57,58] Guidelines were however more likely to be effective if they took account of local circumstances and were disseminated by active educational interventions such as educational outreach.[39]

Audit and feedback on performance, local opinion leaders, rules and incentives have been shown as sometimes effective. Didactic educational meetings and dissemination only strategies such as conferences and distribution of unsolicited materials including clinical guidelines demonstrated little or no effect.[35,39,53,54]

A Cochrane review assessing audit and feedback as a strategy to improve professional practice and healthcare outcomes, concluded that audit and feedback can be effective in improving professional practice, the effects being small and moderate but may be worthwhile.[59] Effects may be larger when HCPs are actively involved with responsibilities for implementing change. Provision of printed education materials, might also modify the effect of audit and feedback.[59] Audit and feedback involving comparison with peers has also been shown to be effective.[59]

Interventions relying solely on passive information transfer are ineffective whilst active knowledge translation strategies are usually effective. Educational outreach and delivery of targeted educational messages by a credible messenger is most consistently effective.[60]

A systematic review of 102 studies indicated that dissemination only strategies such as conferences and mailing unsolicited materials demonstrated little or no change in health care professional behaviour or health outcome. More complex interventions such as outreach visits or opinion leaders ranged from ineffective to highly effective with most being moderately effective. The authors concluded that 'there are no magic bullets for provider behaviour change. A range of interventions can lead to provider change but no single intervention is always effective'.[35] A similar systematic review by the same authors specifically on the effect of continuing medical education (CME) strategies also concluded that effective interventions included reminders, patient-mediated interventions, outreach visits, opinion leaders and multifaceted activities. Audit and feedback and educational materials were less effective and formal CME conferences or activities without practice reinforcing strategies had little impact.[61]

Overall, evidence for interventions aimed at changing health professionals behaviour remains limited and in many cases inconclusive, largely because it is based on evaluation of diverse interventions in terms of the intervention settings, the behaviours or quality improvement targeted and methodological aspects of the studies reported.[47] Interventions aimed at bringing about behaviour change are complex in nature and cannot necessarily be generalised to other situations. The paucity of available evidence for effectiveness reflects difficulties encountered in the evaluation of such complex interventions.[62,63,64]

Effectiveness of different methods to facilitate implementation of evidence in practice are summarised in Table 2.3.

Consistently Effective Methods	Variably Effective Methods	Largely Ineffective Methods
• Educational outreach visits (academic detailing) • Multifaceted interventions • Reminders or prompts (patient-specific) • Audit with feedback and follow-up review • Use of local/national opinion leaders to endorse change	• Audit with feedback only • Local consensus process • Patient mediated interventions • Interventions assessing barriers to change	• Educational materials – passive distribution of recommendations/ guidelines without explanation/follow-up • Didactic educational meetings

Table 2.3. Effectiveness of Methods to facilitate implementation of evidence in practice

2.3.1 Academic Detailing (Educational Outreach)

The evidence for interventions which influence behaviour change in practice suggests that the most consistently effective approach is through academic detailing. The approach is based on 'social marketing' theory, or, the selling of ideas rather than physical products to achieve health and social solutions.[39,60]

Soumerai and Avorn originally defined the principles of 'academic detailing', also known as 'educational outreach'.[65] They noted that a number of theories and principles of communication and behaviour change underlay the success of the pharmaceutical industry in influencing prescribing practices. Despite this, there was little in the literature at the time about the approaches adopted by pharmaceutical representatives or how these may be adapted to the non-profit sector to reduce inappropriate prescribing. They therefore set out to determine the aspects of detailing which could be utilised in supporting physicians in making better therapeutic decisions.

They focused on approaches to improving prescribing behaviour for example by using drugs with better safety profile, decreasing use of marginal therapies, reducing prescribing in vulnerable groups and making more cost effective prescribing choices and ultimately demonstrated changes in prescribing behaviour. [65] In their study two brief visits to physicians by clinical pharmacists reduced inappropriate prescribing of a number of drugs by 14% compared with control ($p \leq 0.0001$).[66]

Soumeri and Avorn consequently defined the key techniques or elements incorporated in the academic detailing approach, which necessarily, involves face to face communication with the practitioner.[66,67]

These include:

- Investigating the baseline knowledge and motivation for current prescribing patterns
- Focusing detailing programmes on specific categories of physicians
- Defining clear educational and behavioural objectives
- Establishing credibility through a respected organisational identity, referencing authoritative and unbiased information sources
- Stimulation of active physician participation in educational interactions
- Use of concise graphic educational materials
- Highlighting and repeating essential messages
- Providing positive reinforcement of improved practices in follow-up visits.

Elements of an outreach visit may vary. However, selection and training of academic detailers is crucial to the success of this approach.[66]

2.3.1.1 Evidence for the Effectiveness of Educational Outreach Visits

Educational Outreach Visits (EOVs) have been identified as having the potential to improve the practice of healthcare professionals. EOVs rely on a personal visit by a trained person to health care professionals (HCPs) in their practice environment. This face-to-face communication may also be referred to as academic detailing or educational detailing. It may include feedback on performance.

The Cochrane EPOC Review Group specifically assessed the effects of educational outreach visits on professional outcomes. In the review, an EOV was defined as a personal visit by a trained person to healthcare professionals in their own settings.[68] The review included 69 studies involving more than 15,000 HCPs. Effects varied depending on types of behaviour being evaluated. However, the results were consistent in demonstrating effects relating to prescribing but varied for other types of performance.

For interventions aimed at changing prescribing behaviour, the authors concluded that EOVs alone or when combined with other interventions have effects that are relatively consistent and small to moderate, but potentially important.[68,35]

They recommended six aspects for consideration for future research into EOVs:

- It is important that investigators report each of the components of the intervention in detail, including the type of visitor and the content of the visits. (Sustained efforts to improve practice might be more effective and efficient than one-time efforts).
- As effects of EOVs are generally small/moderate, studies should be powered sufficiently to detect small but important effects.
- Process evaluation embedded in trials should support determination of the extent to which the intervention was implemented and how it improved practice
- Including patient outcomes as well as professional performance should be considered.
- Evaluation should consider the number and nature of behaviours targeted for improvement as targeted behaviours requiring a large number of steps may be too complex to interpret.
- If found to be effective, where possible, studies should measure use of resources and include economic analyses.

2.3.2 Evidence for the Impact of Pharmacists in Influencing Prescribing Behaviour

Pharmacists are experts in medicines use. Numerous studies have reported the impact of pharmacists from differing backgrounds and experience on prescribing and medicines use in various settings and circumstances.

Community Pharmacists have long influenced prescribing behaviour at individual patient level through initiatives such as medication review, repeat prescribing and disease management.[69,70,71,72] Community pharmacists undertaking sessional work in practices have been shown to influence practice prescribing through assessing their clearly documented interventions including patient review.[69] Case conferences involving community pharmacists with GPs resulted in uptake of significantly more clinically relevant recommendations compared with written feedback alone.[70] Improvement in patient knowledge, medication use and clinical measures have been demonstrated when community pharmacists have been instrumental in delivering structured pharmaceutical care plans for patients with long term conditions.[72]

Early evidence for primary care clinical pharmacists has also demonstrated their impact working within GP practices and influencing prescribing behaviour. Although changes have often been measured by cost savings, promotion of more rational or cost-effective prescribing was the foundation of many initiatives.[73,74] Despite initial reservations, (Canadian) physician perspectives of pharmacists integrated into family practice, providing medication assessment, drug information, academic detailing and practical enhancements are positive and benefits of collaborative working have been realised.[75,76,77] Primary care pharmacist led disease management and patient consultations have also improved medication use and influenced patient care at both individual and practice levels.[78,79,80,81]

As PCTs emerged through NHS reforms, PCT prescribing advisers became the mainstay of prescribing support to GPs locally, promoting high quality prescribing and value for money within the context of wider healthcare.[82] As PCT responsibilities in development and delivery of local services increased, primary care pharmacists now embrace a broad range of roles across a wide range of agencies.[83,84]

Practice visits to promote rational cost effective prescribing and providing prescribing feedback became an established means of communicating with GPs. UK studies have demonstrated that such practice (outreach) visits by pharmacists providing feedback specifically on prescribing cost and volume indicators using comparative ePACT data had some influence on prescribing behaviour.[85,86,87,88] Additional elements of some interventions included discussion around rational drug use and prescribing recommendations. Face to face discussions appeared more successful in reducing inappropriate prescribing than printed information.[85,86,87] Limitations regarding these studies were that outcome measures were generally based on cost rather than the appropriateness of prescribing based on available evidence.

A limited number of studies have specifically evaluated the effect of educational outreach (or academic detailing) by pharmacists on prescribing behaviour. The majority were conducted in the southern hemisphere. Most also evaluated compliance with guidance/guideline recommendations or reduction in costs rather than incorporation of evidence-based practice into clinical decision-making. Many have documented limitations relating to design and evaluation of the intervention.

2.3.2.1 Evidence for the Impact of Pharmacists Using Academic Detailing

In one Australian study, educational mailing plus project pharmacist visits delivering campaign messages to GPs, demonstrated significantly improved compliance with antibiotic guideline recommendations in the intervention group compared with control.[89] Another Australian study providing antibiotic prescribing guidelines plus a brief visit from a clinical pharmacist demonstrated a significant difference in prescribing of preferred antibiotics in the intervention group compared with control.[90]

Three Tasmanian studies by the same authors, separately evaluated appropriate prescribing of allopurinol, NSAID and antibiotics.[91,92,93] Each involved provision of educational material on the specified topic. A pharmacist then visited to discuss rational prescribing of the medications with each GP. Statistically significant differences in prescribing were demonstrated in each study. The authors concluded that educational programmes utilising academic detailing by clinical pharmacists can modify prescribing practices within the community setting. A further Tasmanian study demonstrated that a multifaceted approach employing educational outreach visit plus educational materials, guidelines, feedback and reminders also produced statistically significant increase in the use of osteoporosis therapy in long term oral corticosteroid users.[94]

Educational outreach by clinical pharmacists providing prescription analysis and feedback, report interpretation, therapeutic bulletin plus locally preferred prescribing list in New Zealand resulted in reduced prescribing of benzodiazepines and a significant increase in use of preferred medicines.[95]

One Australian study in which GPs received academic detailing visits from experienced teaching-hospital clinical pharmacists who developed evidence-based presentations on the pharmacological management of heart failure and osteoarthritis demonstrated improvements in prescribing of appropriate medications. However, the small sample size limited comprehensive statistical analysis.[96]

Asthma symptom scores were significantly improved ($p<0.03$) in a more recent South African disease management study. Intervention practices received two EOVs from pharmacists trained in academic detailing, who also left materials describing key interventions to improve asthma care. Control practices received written copies of the guidelines.[97]

Relatively few studies in the UK have investigated the effects of pharmacists in improving prescribing behaviour. None explicitly investigated uptake of evidence-based practice. One early study investigated the use of academic detailing using detail aids to encourage rational approach to prescribing of NSAIDs. The intervention produced a significant increase in prescribing (costs) of the preferred NSAID in the intervention group compared with control.[98] A cluster RCT in twenty GP practices of mailed guidelines versus mailed guidelines plus educational outreach visits from trained community pharmacists on prescribing of recommended NSAIDs, showed no significant differences between groups.[99] One small UK study (two practices) indicated that provision of therapeutics advice by a clinical pharmacist and consultant pharmacologist using educational outreach improved management of hypertension, atrial fibrillation and guideline adherence.[100] Another study assessing the impact of an educational outreach campaign (IMPACT) led by primary care pharmacists on depression management influenced prescribing behaviour in terms of adherence to NICE guidance and cost-effective prescribing of antidepressants.[101]

In the UK, the larger EBOR study evaluated acceptability and effectiveness of outreach visits by community pharmacists using evidence-based practice guidelines to promote change in prescribing. Pharmacists trained in guideline content and detailing techniques performed two visits on guideline topics for four commonly used interventions. Overall there was an (5.2%) improvement in number of patients treated according to the guidelines. Results ranged from +7% (aspirin) to -3% (NSAIDs) depending on the guideline.[102] The study design and interpretation has however been open to criticism. Guideline compliance was evaluated by practice level data collection (not ePACT). A post hoc evaluation of EBOR reported complex interactions between pharmacists, GPs and guideline topics with many influences and barriers affecting uptake of each guideline.[103] The authors recommended that future interventions use a range of methods to explore steps leading to behaviour change.

The Norwegian RaPP study evaluated a multifaceted intervention (educational outreach, audit and feedback, computerised reminders) delivered by pharmacists to support guideline implementation and promote uptake of evidence-based research findings into clinical decision-making. There was an increase in adherence to guideline recommendations on choice of antihypertensive drug but no difference in secondary patient-oriented outcomes.[104,105] An economic evaluation of RaPP however predicted modest savings over two years, as the preferred drug was cheaper.[106]

In an attempt to address current lack of evidence, two Italian RCTs were proposed to test evidence-based methods, academic detailing and pharmacist outreach visits on a large scale and to make independent and evidence-based information available to GPs.[107] One study aimed to evaluate one-to-one (pharmacist–GP) meetings plus information format (the other, to evaluate small group meetings). One hundred and fifty primary care groups were to be randomised to primary care pharmacist outreach visits on one of two topics, aiming for a 10%-15% decrease in prescribing of targeted drugs. GP knowledge and attitudes were to be assessed through a questionnaire. There was however no control (non-intervention) group and it is possible that confounding may have occurred because each group received one intervention. Further details are not accessible, however, comment by the authors provided in an abstract published since the original literature review suggested that the feasibility and acceptance of the proposed Italian strategy may have been high with significant impact on certain prescribing outcomes.[108]

Only one RCT has specifically evaluated individual versus group detailing and demonstrated that both individual and group visits decreased prescribing of highly anticholinergic antidepressants in elderly people compared with control (no visits).[109] Practice visits engaging GPs as a group (as typically occurs in practice) is considered to be a suitable and more cost effective approach to influencing prescribing behaviour than visits with individual GPs and will be employed in this study.

Evidence for influencing prescribing behaviour by pharmacists using outreach visits and academic detailing remains weak, particularly in the UK. However, the evidence does suggest that pharmacists with clearly stated clinical and communication skills are most likely to be successful at bringing about behaviour change in prescribing.[110] Targeted visits are more likely to be effective than untargeted visits.[110,111] It is therefore intended in this study to address inconsistencies in study design and lack of rigour apparent in the currently published studies.

In general, studies evaluating the impact of pharmacists or other health care professionals on prescribing behaviour are quantitative, focusing on prescribing data and identifying shifts in prescribing. Most qualitative studies however, tend to focus on physicians perceptions of and barriers to EBM.[44,45,46,47,48] As far as the researcher is aware, only one (Israeli) qualitative study has evaluated the impact of an EBM teaching intervention on primary care physicians' point of care behaviour.[112] The teaching emphasised accessing, appraising and integration of best evidence into practice. Although it affected attitudes and knowledge it had little impact on the physicians' ability to use pre-appraised resources at the point of care because of the complexity and impracticality of use in a busy setting. Constantly changing evidence was also perceived as hindering the practice of EBM. The study identified a need to improve ease of access to evidence-based resources.

This study will use pre-appraised evidence-based information in face-to-face communication with primary care pharmacists thus removing the burden for GPs of seeking evidence at the point of prescribing.

Not all sources of information (including guidelines) are transparently linked to the underlying evidence base and they do not necessarily represent a critical appraisal of the evidence. It is important to ensure that clinicians continue to have access to appropriate sources of evidence, evidence summaries and guidelines that acknowledge the most current EBM thinking. Primary care pharmacists are in an ideal situation to access the evidence and communicate the most up to date evidence based prescribing information.

2.4 Primary Care Pharmacists

Pharmacists are key players in the management of medicines. They are highly skilled and trained professionals possessing greater expertise in medicines than any other health professional as highlighted by the RPSGB.[113]

The most visible face of the pharmacy profession is the community pharmacy situated in the high street, with most if not all members of the public accessing pharmacy professional services through their local community pharmacist. Hospital pharmacists are also pivotal members of the healthcare team where their clinical role has become increasingly extensive and specialised, involving direct management of patient's medicines and, in making independent prescribing decisions.[113,114] Other pharmacists work within the pharmaceutical industry and in academia playing a crucial role in the discovery and development of new drugs and medicines.

A more recent development in the professional role of the pharmacist has been the evolution of primary care pharmacists also known as 'prescribing advisers'. In 2008, out of 25,243 registered pharmacists who were actively working in the UK, just 7.2% of pharmacists were actively employed in primary care. The majority (71%) were working in community pharmacy, 21.4% in hospital, 4.1% in industry, 2.8% in academia and 3.8% elsewhere.[115]

Pharmacist's skills have long been recognised. However, it has been acknowledged that in many areas, pharmacists' knowledge and skills have been underutilised.[116,117,118,119]

Government has increasingly sought to utilise pharmacist skills more effectively in both hospital and primary care. In primary care however, the emphasis to date has largely focussed on greater integration of community pharmacists in activities to meet national policy objectives by improving access to medicines, medicines services and medicines advice through the national community pharmacy contractual framework.[117,119]

The government acknowledges that primary care PCT prescribing advisers are increasingly active in promoting cost effective use of medicines both at PCT and practice level. It also notes that PCT pharmaceutical advisers make a significant contribution to local prescribing strategies, are involved in commissioning of drug treatments, are increasingly working with secondary care pharmacists and have a role in implementation of the community pharmacy contractual framework.[118]

2.4.1 Evolution of the Primary Care Pharmacist

Historically, Health Authority medical and pharmaceutical advisers have been the mainstay of prescribing support to GPs at local level. The evolution of Primary Care Trusts (PCTs) as part of NHS reform in 2000 has meant that cost effective prescribing has become high priority requiring professional support.[120] Consequently, since the 1990's, the role and function of primary care pharmacists has evolved markedly within the NHS.[83,84]

The NHS requires that emphasis is placed on high quality, evidence based medicine including prescribing.[1,2] As the prescribing adviser role has expanded, this has involved evolution of comprehensive Medicines Management Services within PCTs. Pharmacists because of their training are equipped to support delivery of this

agenda and are the professional leads within the function. They also fulfil a strategic role, focusing on maximising benefit and minimising risk of medicines, as well as making the best use of resources allocated for medicines.

Early resources intended to define PCT Medicines Management responsibilities and to support prescribing advisers in achieving quality prescribing objectives in primary care were issued by the National Prescribing Centre and other sources.[9,121] Many prescribing advisers also used the National and Primary Care Trust Development Programme (NatPaCT) Competency Framework self-assessment and support tool to develop and evaluate their PCT Medicines Management strategies.[122] The NPC has continued to be an important resource for individual prescribing advisers, prescribers and commissioning and provider organisations on prescribing and medicines management issues impacting on primary care. (Section 2.5)

2.4.2 Medicines Management Role and Function

PCTs should have an appropriate infrastructure in place to manage prescribing in primary care and across the primary and secondary care interface. An essential aspect of successful medicines management involves promotion of rational, cost-effective prescribing in line with local and national priorities such as National Service Frameworks (NSFs) and NICE Guidance in order to maximise health gain.[123]

Key Medicines Management functions involve promotion of evidence-based prescribing and influencing prescribing behaviour. Medicines Management activities may be implemented at practice and organisational level, as well as spanning primary, secondary and tertiary care interfaces.

In order to facilitate prescribing change, Medicines Management activities frequently involve GP practice visits, audit and provision of prescribing feedback as well as provision of synthesised evidence-based information often disseminated as guidelines, newsletters and PCT policies and may involve prescribing support from pharmacists / pharmacy technicians, working directly with and within practices.

Organisational level activities include facilitation and involvement in local therapeutic networks and primary/secondary care decision-making committees and educational initiatives for local healthcare professionals.

In England, primary care pharmacists also play a significant part in Practice Based Commissioning (PBC). Evolution of the role is set to continue. As the NHS embarks on further reorganisation, Local Commissioning Groups will control the commissioning of services as well as taking responsibility for the integration of medicines management functions into the new commissioning organisations.

2.4.3 Influencing Primary Care Prescribing

The National Audit Office (NAO) report 'Influencing Prescribing Cost and Quality in Primary Care' published in 2007 provided prescribing advisers in PCTs with suggestions on how to drive clinical and cost effective prescribing initiatives through more effective planning of communication and targeting of clinicians.[11] Results from a separate qualitative study into GP prescribing behaviour based on interviews with PCT managers and focus groups with GPs also contributed to the report.[124]

The NAO report advises that the most effective method of communicating with physicians is to visit them, and by making the most of each visit. This involves building relationships, monitoring performance and following up with them in order to

facilitate change. A number of the more effective approaches adopted by pharmaceutical industry are highlighted in the report with suggestions on how they may be adapted by prescribing advisers in order to influence prescribing behaviour and drive change in primary care (although evidence for their success is not provided in the report).

The report addresses areas such as effective communication, targeting effort effectively to the practices that need it most, building relationships and getting plans adopted by clinicians in order to bring about change in line with the Medicines Management agenda. The NAO stresses that visits have more impact if communication materials such as prescribing data and 'communication pieces' (or 'detail aids') are available to reinforce the prescribing strategy. Examples of written materials which may be used to support communication of key messages (developed by the Department of Medicines Management, Keele) are included.

In summary, the methods embraced by pharmacists in influencing prescribing within their role are multifaceted and may be employed with varying success. Although not strictly defined as a strategy, the resulting model may be considered as integration of known successful approaches with social influence strategies for promoting evidence-based medicine in prescribing. Evidence for the impact of this approach as such is lacking and remains to be tested and therefore forms the basis of this study.

2.4.4 Primary Care Pharmacist Competencies

In order to support the development and functions of primary care pharmacists, the National Prescribing Centre (NPC) has developed a Core Competency Framework for Primary Care Pharmacists. First published in 2000 it identified the skills and behaviours individual pharmacists need to in order to contribute effectively within primary care.[83] Updated in 2003 it was incorporated in the 'NPC PCT responsibilities around prescribing and medicines management scoping and support guide'.[9,84]

The core competency framework is regarded as generic in that the competencies can be applied to all pharmacists working in primary care. However, it is possible to define primary care pharmacist roles into three general levels as described in the framework, in order to apply the competency framework to individuals. These are broadly defined as:

- Level 1 - A practice based pharmacist
- Level 2 - A senior primary care pharmacist
- Level 3 - A Chief Pharmacist / Head of Medicines Management

Primary care pharmacists involved in delivering initiatives as described in the NAO report require considerable clinical and communication skills and would therefore be expected to demonstrate skills defined at Level 2 and to be operating at that level. Key competencies required at this level include sound clinical therapeutic knowledge, communication and other interpersonal skills, knowledge of health policy and priorities, and skills in the management of change.

2.5 Prescribing and Medicines Management Support

2.5.1 The National Prescribing Centre

The National Prescribing Centre (NPC) has been one of, if not the main provider of robust evidence-based prescribing, therapeutics and medicines management information across the NHS. Since its formation in 1996 by the Department of Health, the NPC evolved from its early beginnings to provision of wide based support of Medicines Management functions, predominantly in primary care, whilst adapting to continuing structural, policy and priority changes occurring within the NHS. Its aim being, to support individuals and the NHS to deliver rational, evidence-based, safe and cost-effective use of medicine for the benefit of patients and the public.[125]

The NPC had developed a wide range of resources, including e-learning and organisation of learning events and activities which support and promote evidence based Medicines Management across the NHS.

More recently, as new NHS structures have emerged and transferred to GP Commissioning Consortia, the NPC has been instrumental in defining key functions and organisational competencies in relation to prescribing and medicines management and in developing associated resources. The NPC published several significant guidance documents in order to support achievement of key Medicines Management objectives in primary care.[10,125,126,127]

The NPC also traditionally supported the therapeutic training for pharmacists working in primary care by cascaded delivery of local therapeutic workshops.

From 2003, specific training was commissioned and delivered through the 'NPC Plus' programme, launched to extend the support offered to local NHS organisations and providers of NHS healthcare. The aims and objectives of NPC Plus include delivery of high quality, effective healthcare by supporting healthcare practitioners and service providers, including the provision of individual and organisational training for Prescribing and Medicines Management.[128] From 2006, NPC Plus operated from within the Faculty of Health, Keele University.

2.5.1.1 NPC Plus Therapeutic Workshops

NPC Plus Therapeutic workshops have supported an evidence-based approach to healthcare and up-to-date evidence-based education, on a wide range of therapeutic topics delivered by a team of NPC Plus Therapeutic Trainers operating across the UK.[128] They are highly knowledgeable healthcare professionals who have been trained, assessed and supported by the National Prescribing Centre's Evidence-based Therapeutics Team, thus maintaining the high level of competency required of an NPC Plus trainer.

NPC trainers (usually pharmacists) have a unique combination of knowledge, experience and expertise and can tailor workshops to local need and context. Training is underpinned by evidence-based materials produced by the NPC and which are also subject to rigorous quality assurance procedures.[129]

In April 2011, the NPC became part of the National Institute for Health and Clinical Excellence, and from May 2012, became integrated in the NICE Medicines and Prescribing Centre. The NPC's activities are now incorporated within the NICE work

programme. Following merger with NICE, the original NPC resources, publications and e-learning materials have been made accessible from a separate NPC Legacy website.[130] NPC Plus closed in July 2012 following review between NICE and Keele University. The trainer programme is pending further review before being incorporated into the work of NICE.[131] All NPC resources and training accessed for the purposes of this study were accomplished before the formal transfer of NPC activities to NICE.

2.5.2 Information Mastery

It is becoming increasingly difficult to access relevant and evidence-based information to inform clinical decision-making with an ever increasing volume of available information, fuelled partly by the expansion of the internet. Clinicians cannot hope to keep abreast of current published evidence by searching and evaluating it themselves. They require some means of developing effective and efficient ways of accessing and evaluating useful information in order to keep up to date.[132,133]

A probable confounding factor involves an educative system whereby clinicians (doctors in particular) initially learn through a directed pedagogical process but lack and are not taught the necessary skills to be able to access and discriminate relevant information in order to further learn and update themselves.[134]

The concept of Information Mastery, as a means to combat 'information overload' was first described by Slawson and Shaughnessy and has been defined as the "applied science that allows clinicians to harness resources in the information age".[134,135] Information Mastery depends on using strict criteria, so that clinicians can focus on obtaining information which will be most useful to them for clinical situations.[136] In order to establish usefulness, information sought must be relevant to everyday practice, it must be correct (valid) and should be easy to obtain.[136,137]

Techniques for accessing relevant and valid information are based on 'hunting', foraging and 'hot-synching'.[133] Hunting relies on having a reliable system for accessing relevant and valid data to answer a question specifically and quickly. Foraging requires having a reliable system to highlight new, important, relevant and valid information which may require a change in practice. Hot-synching involves actively checking and updating personal knowledge and skills periodically for the main conditions seen in practice.

In adopting these techniques, HCPs should use trustworthy, pre-appraised summaries of information. Reliable sources in the UK are regarded as NICE, NHS Evidence, Cochrane Library, Clinical Evidence, InfoPoems, MeReC and the Drug and Therapeutics Bulletin (DTB).[133]

The NPC promotes the principles of Information Mastery and offers a variety of tools to help professionals cope with information overload. It supports busy practitioners in keeping up to date with the clinical evidence base, health policy and other types of information.[133] It produces pre-appraised, synthesised information including MeReC publications which are available electronically. MeReC Rapid Review is a 'foraging' tool, providing critiques of key clinical trials or guidance as soon as they are published. MeReC Monthly provides a compilation of key MeReC Rapid Reviews. The quarterly MeReC Bulletin, focuses on key therapeutic dilemmas, collating and summarising the available evidence and guidance. MeReC Extra, (also quarterly) summarises other MeReC publications and highlights new e-learning materials on the NPC website.

2.5.3 Electronic Updates

'Foraging' involves accessing evidence from trusted sources, typically by receiving electronic alerts and updates from reliable sources such as the NPC electronic Current Awareness Bulletin (eCAB) and the National electronic Library of Medicine (NeLM) as soon as information is published. eCAB accesses information from other relevant websites (including NeLM, NICE, Cochrane,) and collates information for dissemination through its daily and weekly alerts to subscribers.[138] It also provides links to the original websites where more detailed information can be accessed.

NeLM is the largest medicines information portal for healthcare professionals in the NHS and is updated daily. It promotes safe and efficient use of medicines and provides evidence based reviews on drugs and drug therapy. It also critically reviews evidence and produces specific drug reviews, drug class reviews and disease-focused reviews.[139] Much of the content is developed by pharmacists working in the NHS UK Medicines Information Service.

All pharmacists involved in the study subscribed to eCAB e-mail alert services as part of their role in primary care and would have been alerted to newer evidence and publications relevant to the study therapeutic topics arising during the intervention period.

In general, doctors remain unskilled in Information Mastery.[134] In contrast, it is believed that many primary care pharmacists (including those involved in the study), have developed and honed their Information Mastery skills in supporting rational and evidence based prescribing as a core part of their role.[9] Many have taken advantage of NPC Information Mastery training and employ these skills, including critical appraisal, which involves evaluating available evidence to inform all aspects of the Medicines Management function from development of medicines management policy to individual patient decision-making.

2.6 Complex Interventions

Interventions intended to change health professionals' behaviour are by definition complex. In health care, Complex Interventions may be targeted at individual patient or health care professional level. Alternatively, they may be targeted at an organisational or service modification, or delivered at a population level as often implemented in public health campaigns.

Complex Interventions are defined as comprising a number of separate elements containing several interacting components.[63,64] There are also several dimensions of complexity which may relate to:

- number of and interactions between components within the intervention
- number of and difficulty of the behaviours required by those delivering or receiving the intervention
- group or organisation targeted
- number and variability of outcomes
- whether a degree of flexibility or tailoring of the intervention is permitted.[63,64]

Consequently, evaluation of a complex intervention may present difficulties relating to standardisation of the design and delivery of the intervention.[62,63,64] Evaluation frequently requires application of quantitative and qualitative approaches.

The Medical Research Council (MRC) has developed a framework to provide guidance on the development and evaluation of complex interventions. The framework re-emphasises key messages and addresses limitations of earlier guidance and considers more recent experience and evidence for the implementation of complex interventions.[64] One aim of the guidance is to support researchers in choosing and implementing appropriate methods to evaluate an intervention.

The intervention being tested in this research is the impact of primary care prescribing advisers in influencing GP prescribing behaviour and is regarded as a complex intervention because of the level of complexity inherent in influencing prescribing behaviour. The approach described in the MRC Guidance was therefore adopted as a basis for developing, defining and evaluating the intervention to be tested in this study.[64]

When developing and evaluating complex interventions it is important to ensure sufficient development and pilot work, and consideration of the practicalities of its implementation.[63,64] It is important to clearly define each of the individual components of the intervention, prospectively and, as far as possible, to standardise the approach adopted by the individuals involved in delivering the intervention in order to ensure consistency and reproducibility. It is also necessary to define who the intervention is aimed at and any change expected to be achieved. Ideally, an exploratory trial should be randomised to allow assessment of the size effect which will provide sound basis for calculating sample sizes for any larger trial.[64] It is not unusual to also include a qualitative assessment in order to gain insight from the individuals involved, including identification of barriers to participation and adoption of the intervention.

Chapter 3

Theoretical Basis and Study Rationale

This chapter describes the rationale for conducting the study and why it constitutes an evaluation of a complex intervention. It explains the hypothesis to be tested in evaluating the defined complex intervention. The aims and objectives of the research are summarised here. The methods applied in the evaluation and the main outcome measures are introduced here, as is the basis for the study design, which adopts a mixed methods approach. The latter part of this chapter also contains a summary of the evidence underpinning the two therapeutic topics which were defined for evaluation of the intervention.

Evidence for efficacy in influencing prescribing behaviour is limited, and is not necessarily generalisable to the UK healthcare system.[68] Evidence for pharmacists influencing prescribing behaviour specifically using outreach visits and academic detailing is also lacking, particularly in the UK. However, available evidence does suggest that pharmacists with clearly stated clinical and communication skills are most likely to be successful at bringing about behaviour change in prescribing.[110]

Not all sources of information available to clinicians are evidence-based. Published information claiming to provide clinical evidence has frequently not been critically evaluated and there is often a lack of transparency relating to the underlying claims for efficacy.[29] It is appropriate that clinicians have access to relevant sources of evidence, evidence summaries and guidelines that acknowledge the most current EBM thinking.

Typically, primary care pharmacists are skilled in accessing and evaluating evidence about effectiveness and safety of medicines and already have a responsibility in influencing prescribing behaviour. They are in an ideal situation, to communicate key clinical messages and promote the uptake of evidence-based findings a role which many currently undertake. The effect of their influence on incorporation of the evidence-base into prescribing related decision-making however remains less clear.

The hypothesis for this study is that implementation of an intervention utilising strategies which are known to work in changing healthcare professional behaviour and aimed at bringing about change in practice will influence prescribing behaviour according to the EBM paradigm. The intervention, aimed at general practitioners is multifaceted in nature. The intervention is based on outreach visits conducted by trained clinical pharmacists employing an academic detailing approach. The components of this complex intervention will also incorporate interactive discussion around evidence-based therapeutic topics supported with provision of topic summaries highlighting key messages and audit data and feedback on practice prescribing trends.

This study aims to address Cochrane recommendations by utilisation of effective strategies (multifaceted approach involving interactive rather than didactic educational meetings, audit, feedback and summaries of key messages) in influencing behaviour change and by employing sustained efforts to improve prescribing behaviour, rather than individual visits and by clearly defining the type of visitor and visit content.[59,68] Pre-appraised evidence-based information will be utilised in face-to-face communication by primary care pharmacists thus removing the burden for GPs of seeking evidence at the point of prescribing. It is intended that this study also address inconsistencies in study design and lack of rigour apparent in the currently published studies.

A mixed methods approach will be adopted for evaluation of the intervention. A quantitative evaluation of changes in prescribing relating to two predetermined therapeutic topics will be made. Cochrane also recommends consideration of patient outcomes as an evaluation measure and a further quantitative evaluation will be performed in an attempt to identify any change in patient related outcomes.[68]

A qualitative evaluation of GP perceptions, attitudes and beliefs will be undertaken to provide greater insight into intervention delivered. It aims to establish whether the intervention influenced the way GPs worked. It will also assess pastoral aspects, whether the GPs valued the intervention and whether they developed as a result. It is hoped that the results obtained through this mixed methods approach may inform future medicines management strategies for influencing prescribing behaviour.

This study adopts the principles described in the guidance on developing and evaluating complex interventions.[63,64] It is therefore exploratory in that it aims to describe the individual components of a replicable intervention, testing feasibility and delivery of the intervention in everyday practice, and its impact on and acceptability to participants. It seeks to demonstrate that the intervention can be delivered as intended. Pragmatically, as the sample size is relatively small, this study will also enable assessment of size effect and sample size for any future studies.

3.1 Study Aims and Objectives

An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Research Aim

To evaluate a complex intervention utilising primary care pharmacists intended to influence GP prescribing behaviour by promoting uptake and integration of evidence based practice in prescribing.

Research Objectives

- To assess the impact of evidence-based prescribing support delivered by primary care pharmacist prescribing advisers on GP prescribing outcomes compared with non-intervention practices.

- To assess the impact of evidence-based prescribing support on measurable patient-orientated outcomes and to determine whether the intervention leads to improved patient care.

- To explore GP perceptions, attitudes and beliefs regarding prescribing support both before and after delivery of the intervention.

- To consider the feasibility of implementing the intervention more widely.

The study also seeks to define a consistent, reproducible intervention (and its components) for evaluation and potential implementation. The evaluation seeks to confirm the reproducibility and fidelity of the intervention in practice and that it was delivered as intended.

3.2 Description of the Intervention

The purpose of the intervention was to influence prescribing behaviour by adopting a number of known (evidence-based) approaches for influencing behaviour change. The intervention centred on regular interactive practice meetings (outreach visits) conducted by pharmacist prescribing advisers with GPs in their practices. Academic detailing techniques were adopted in the promotion of evidence-based prescribing.

A fundamental objective of the study was to develop and deliver a clearly defined complex intervention for evaluation. The intervention and its components were defined in line with MRC Guidance on Complex Interventions. It was important therefore to define the individual components of the intervention and to standardise the approach adopted by the individuals involved in its delivery in order to ensure consistency and reproducibility.

Intervention Components

- Pharmacist Prescribing Advisers instrumental in delivery of the intervention

- Regular Practice Visits during 12 months
    - Baseline visit.
    - Three Follow-up visits – each approximately 3-4 months apart.

- Academic Detailing Approach
    - Engagement of healthcare professionals in interactive discussion focussing on pre-determined therapeutic topics (T2DM, NSAIDs)
    - Use of Detail Aids
    - Re-enforcement of key messages

- Provision of evidence-based prescribing support
    - Clinical pharmacists supporting evidence-based prescribing in predetermined therapeutic topics
    - Use of Detail Aids - Content based on best available evidence
    - Provision of evidence-based summaries on therapeutic topics
    - Access to and dissemination of appropriate evidence-based resources

- Audit and feedback to practitioners during study period
    - Provision of regular and updated comparative prescribing data
    - Written Visit Report from pharmacist following each practice visit. To highlight visit content, discussion and agreed actions

- Pharmacists involved in the intervention
    - Meet NPC Level 2 competencies for pharmacists working in primary care
    - Trained in Academic Detailing techniques
    - Sound clinical and therapeutic knowledge
    - Updated training in therapeutic topics and Information Mastery
    - Communication and interpersonal skills

3.3 Therapeutic Topics

The latter part of this chapter also contains here, a summary of the evidence underpinning the two therapeutic topics which were defined for evaluation of the intervention. These were:

- Therapeutic management of patients with Type 2 diabetes (T2DM)
- Use of non-steroidal inflammatory drugs (NSAIDs) in musculoskeletal conditions.

Background and rationale for their inclusion as a component of the study intervention is summarised in this section with reference to the main published evidence supporting therapeutic interventions to improve patient outcomes.

3.3.1 Type 2 Diabetes

3.3.1.1 Background

Diabetes is an increasing problem in the UK. In 2006, approximately 1.9 million people diagnosed with diabetes were recorded on practice registers in England. An estimated half million remained undiagnosed.[140] In addition to the human cost, the financial burden of diabetes is estimated to be as high as 10% of the NHS expenditure which equates to approximately £9 billion a year.[140]

Prevalence of diabetes in the UK is estimated between 3.5%-5.0%. Approximately 85% of diabetics have Type 2 diabetes (T2DM), which affects approximately 4% of the population.

Despite sharing a similarity of disordered glucose metabolism, manifested by raised glucose levels, Type 1 diabetes (T1DM) and T2DM possess different aetiologies and consequently, different approaches to management. T1DM is an autoimmune disease characterised by pancreatic beta-cell destruction leading to an absolute insulin deficiency requiring exogenous insulin. T2DM is a long-term condition associated with increasing obesity and an aging population usually manifested by insulin insensitivity plus a failure of pancreatic secretion to compensate for increased insulin requirements.

Although characterised by raised blood glucose, T2DM is essentially a cardiovascular disease, associated with increased cardiovascular morbidity and mortality. The three commonest complications are angina, cardiac failure and myocardial infarction. It is also a leading cause of blindness, end-stage renal failure and lower limb amputation. There is evidence that effective management of the disease and associated risk factors increases quality of life and life expectancy. Complications of T2DM can be limited or prevented with good, early intervention. Management of patients with T2DM is multifactorial in approach.

Lifestyle interventions (diet, exercise) are key in the prevention and treatment of T2DM, which aim to correct obesity, improve glycaemic control, blood pressure and blood lipid control. After stopping smoking, successful management of blood pressure is the most effective means of reducing cardiovascular risk in T2DM.[141] Blood lipid management and use of aspirin are the next most effective interventions.[141] The main aims of treatment are therefore to manage symptoms, reduce life threatening or disabling complications (MI, stroke) and manage renal disease, retinopathy and foot disease.

Figure 2. Relationship of reductions in cholesterol, blood pressure and HbA1c with improvements in coronary heart disease (CHD)[a] and cardiovascular (CV) outcomes[9]

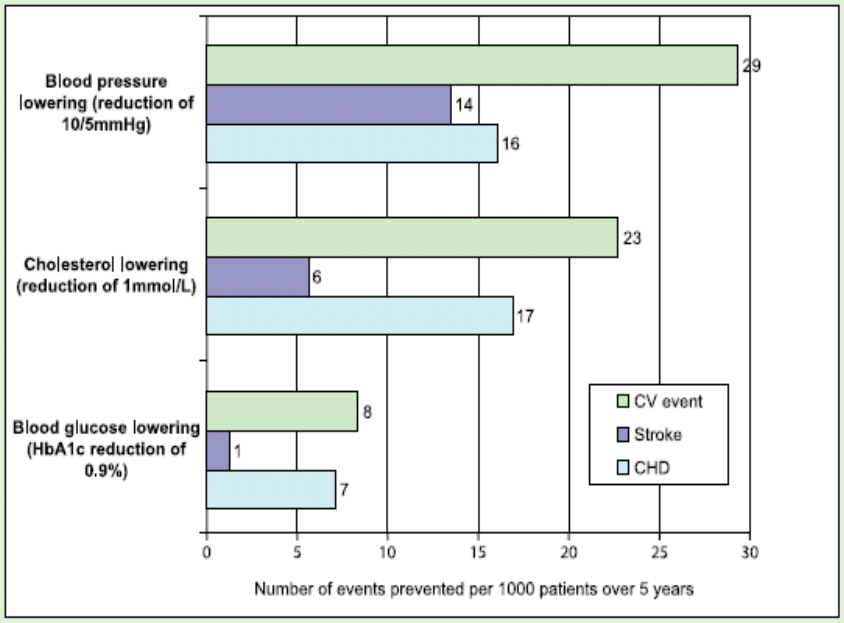


Figure based on Table 1 from Yudkin JS, et al.[9] Data are from CTT meta-analysis[10] (cholesterol lowering), Law MR, et al[11] (blood pressure lowering) and CONTROL meta-analysis[12] (blood glucose lowering). Note that the number of events prevented cannot be added together as the law of cumulative benefits (or diminishing returns) will apply.

[a] CHD is defined as fatal and non-fatal myocardial infarction (MI) and sudden death.

Figure 3.1. Reduction of Cardiovascular Risk in T2DM. Extract from MeReC Bulletin Vol 21 No.5

3.3.1.2 Blood Glucose or Blood Pressure

The landmark United Kingdom Prospective Diabetes Study (UKPDS) was conducted over 20 years in 5012 patients with newly diagnosed T2DM. Key findings were reported and published relating to different study sub-groups.

Intensive control of blood glucose with sulphonylureas or insulin was shown to be important in terms of managing symptoms and reducing microvascular complications (single retinopathy endpoint). The benefit on macrovascular outcomes (MI, stroke) however, was not proven.[142]

In contrast, metformin was shown to have an effect on reducing macrovascular complications which is independent of its blood glucose lowering effect.[143] Metformin is therefore the preferred firstline hypoglycaemic drug in T2DM (NICE).

UKPDS 38 determined whether intensive (lower) blood pressure (BP) control prevents macrovascular and microvascular complications in T2DM. It demonstrated that intensive BP control achieved clinically important reduction in risk of deaths and T2DM related complications.[144] The authors concluded that reducing BP needs to have high priority for patients with T2DM.[144] Intensive control of BP is therefore

regarded as, if not more important than intensive blood glucose control in managing the cardiovascular risks associated with T2DM.

Concerns have been raised however suggesting that data from UKPDS have been distorted by other authors and reviewers continuing to promoting an aggressive approach to glucose control.[145,146,147]

One meta-analysis showed no association between degree of HbA1c reduction and magnitude of risk reduction. The authors concluded that improving BG control without addressing other abnormalities, most importantly hypertension, dislipidaemia, and platelet activity may only produce limited benefit.[148]

Evidence also suggests that Health Care Professionals (HCPs) frequently focus on blood glucose control rather than emphasising the importance of aggressively managing cardiovascular risk factors and that the 'glucocentric' approach to management is prominent.[149,150] T2DM patients are also often unaware of the importance of BP and cardiovascular risk management.[151]

3.3.1.3 Management of Blood Glucose

More recently evidence from three studies (ACCORD, ADVANCE and VADT) has demonstrated that intensive blood glucose lowering failed to show any reduction on cardiovascular events compared with standard treatment and raised concerns that intensive BG control is actually harmful.[141,152,153,154]

The evidence for improved patient outcomes with newer drugs is also lacking as all recently introduced hypoglycaemic agents have been licensed on the basis of their blood glucose lowering ability rather than effect on patient outcomes.

Self-Monitoring of Blood Glucose (SMBG) is crucial in the management of patients with T1DM and T2DM patients on insulin. Evidence also suggests that T2DM patients on oral therapies or who are diet-controlled are unlikely to gain benefit from SMBG as it may result in lower quality of life because of increased level of anxiety.[155,156,157]

Recommended treatment choices for management of blood glucose and target HbA1c levels are summarised in NICE Guidance on management of T2DM.[158]

3.3.1.4 Management of Cardiovascular Disease in T2DM

3.3.1.4.1 Hypertension

Several large RCTs have proven the importance of managing hypertension in both diabetics and non-diabetic patients.[6] In general, there is no compelling evidence of any clinically significant, drug specific effects to distinguish between antihypertensive agents (diuretics, calcium channel-blockers and ACE-Inhibitors) in terms of BP lowering effect (although renin-angiotensin drugs are preferred firstline because of renoprotective effects in diabetics).[6,159,160]

The main focus of therapy is therefore to reduce blood pressure in order to improve cardiovascular outcomes. Greater risk reductions are produced by regimens targeting lower BP goals.[159] Recommended drug choices, sequence of use and BP target levels are summarised in NICE Guidance.[158]

3.3.1.4.2 Blood Lipids

Evidence for management of blood lipids in diabetics largely comes from the Heart Protection Study (HPS) where simvastatin reduced cardiovascular event rates in high risk patients, including diabetics whose cholesterol levels were not raised.[161,162] Evidence from the CARDS study also provided evidence for reduction in cardiovascular events in people with T2DM.[163]

In most patients withT2DM, lipid lowering therapy (usually simvastatin 40mg) should be initiated as first line blood lipid lowering therapy. Target lipid levels are defined in NICE Guidance.[158]

3.3.1.4.3 Antiplatelet Therapy

NICE Guidance, recommends initiation of aspirin in higher risk patients and those aged 50 or older as long as blood pressure is controlled.[158] More recent evidence indicates that aspirin may only be effective in secondary prevention of cardiovascular events rather than as primary prevention.[164]

3.3.1.5 Renal Function

Management and prevention of renal deterioration is an important goal in the management in patients with T2DM. Renin-Angiotensin System (RAS) drugs constitute a key therapeutic intervention for the management and prevention of diabetic nephropathy.

Although classified as antihypertensive medicines, RAS drugs are also licensed for use in heart failure, left ventricular dysfunction, post-myocardial infarction, chronic kidney disease (CKD) and in diabetes. They act by slowing down the development of microalbuminuria and protenuria, reduce progression and hence subsequent deterioration in renal function in patients with T2DM.

3.3.1.5.1 Use of Reno-Angiotensin Drugs in T2DM

The two main classes of RAS drugs are ACE-Inhibitors (ACE-I) and Angiotensin-Receptor Antagonists (A-II-A or ARB).

ACE inhibitors have a more robust evidence base across all indications than A-II-As and there is no evidence that A-II-As are more effective or safer than ACE-Inhibitors in any indication. A-II-As however remain an alternative to ACE-inhibitors if ACE-Is are not suitable.

A Cochrane review concluded that both ACE-Is and ARBs had similar effects on renal outcomes. At maximum tolerated doses however, ACE-Is reduced all-cause mortality but A-II-As did not, providing some evidence for reduced cardiovascular outcomes with ACE-Is but not for A-II-As.[165]

The evidence-based position and current NHS policy is that ACE inhibitors are first-line choice if RAS drugs are indicated.[158,166,167,168]

3.3.1.5 Rationale for Inclusion of T2DM Management as Part of the Intervention

Management of blood glucose is important in patients with T2DM, however, in isolation is not the key to reducing morbidity and mortality.[141,169]

Management of T2DM was included as a therapeutic topic because it is a chronic condition requiring a multifaceted approach. Improved management should ideally lead to appropriate therapeutic intervention for various aspects of the condition, achievement of related targets and improved clinical outcomes.

The key messages underpinning the evidence base relating to management of T2DM delivered within the study intervention were therefore about prioritising management by targeting the most effective approaches in order to minimise cardiovascular risk and to reduce adverse cardiovascular and cardio-renal outcomes. Other key messages revolved around safety and efficacy of newer drugs in diabetes (including glitazones), and assessment of the benefits and risks in using these drugs.

3.3.2 Management of Musculoskeletal Pain

3.3.2.1 Background

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) have wide ranging applications in the management of musculoskeletal anti-inflammatory conditions and pain and may be used in both acute and chronic conditions. Their principle pharmacological effects are analgesic, anti-inflammatory and antipyretic. Serious side effects associated with NSAIDs include gastrointestinal complications (e.g. perforation, ulcer, bleeding), cardiovascular effects (e.g. stroke, myocardial infarction) and cardio-renal effects (e.g. oedema, hypertension, heart failure).

NSAIDs inhibit cyclo-oxygenase (COX) enzymes. There are two main types of COX enzymes, COX-1 which produces prostaglandins which help maintain gastric mucosal integrity and platelet induced blood clotting, and COX-2 which mediates pain and inflammation.

Traditional NSAIDs including ibuprofen, naproxen, diclofenac and indomethacin were developed before the mechanism of action of NSAIDs and COX selectivity was understood. Because of their association with potentially serious gastrointestinal effects, COX-2 selective NSAIDs (also known as coxibs) were subsequently developed with the intention of targeting inflammation and reducing gastrointestinal risk. The first selective COX-2 Inhibitors (celecoxib, rofecoxib) were licensed based on results from two randomised trials.[170,171] However, coxibs were not recommended routinely in patients with cardiovascular disease, because of safety concerns regarding adverse cardiovascular effects.[172,173]

Several traditional NSAIDs were subsequently found to differ in their COX- 1 and COX-2 selectivity with meloxicam and etodolac being regarded as 'partially selective', and diclofenac arguably, now qualifying as a 'coxib' as it preferentially inhibits COX-2 rather than COX-1.[174]

Evidence subsequently emerged however, demonstrating that selective COX-2 Inhibitor use is associated with a considerably higher incidence of adverse cardiovascular events than other traditional NSAIDs (thrombotic risk).[174,175] Consequently, the MHRA has issued a number of warnings on cardiovascular effects of COX-2 selective inhibitors.[176] Rofecoxib, valdecoxib and lumaricoxib have since been withdrawn from the market.

Both traditional NSAIDs and COX-2 Inhibitors have also been the subject of MHRA warnings regarding serious gastrointestinal toxicity, with the elderly and those on aspirin being identified as at greater risk.[177,178]

3.3.2.2 Thrombotic versus Gastrointestinal Risk

Most available evidence relates to diclofenac, COX-2 Inhibitors, ibuprofen and naproxen. Less evidence is available regarding the cardiovascular safety or efficacy of the partially selective NSAIDs.

Evidence has now evolved demonstrating that diclofenac is associated with a similar level of cardiovascular risk as COX-2 Inhibitors. Further MHRA advice re-iterates concerns regarding cardiovascular risk associated with COX-2 Inhibitors, including diclofenac use.[179,180] Naproxen and (low dose) ibuprofen are not associated with

increased cardiovascular risk although higher dose ibuprofen may be associated with a small increase in thrombotic risk.

Ibuprofen is known to be associated with lower gastrointestinal risk than diclofenac or naproxen.[174] Other traditional NSAIDs are known to carry higher gastrointestinal risk.[180] Proton pump inhibitors (PPIs) may be co-prescribed in order to reduce adverse gastrointestinal effects associated with NSAID use.

All non-steroidal anti-inflammatory drugs (NSAIDs) including COX-2 Inhibitors are associated with a range of adverse effects on gastrointestinal, cardiovascular and renal systems which can be serious and life threatening.

Evidence continues to emerge highlighting safety concerns regarding these drugs, particularly in the elderly.[174] The MHRA has continued to monitor NSAID use, issuing issue both warnings and advice regarding use of NSAIDs and COX-2 Inhibitors.[181,182,183] The MHRA has advised using the lowest dose for the shortest duration possible if prescribed. It also advises against using these drugs in patients at risk of renal impairment (particularly the elderly).[182,183]

3.3.2.3 Clinical Management

The key approach to management of patients where prescribing of NSAIDs is being considered, is to focus on minimisation of risk to the patient, taking into consideration individual patient factors. Gastrointestinal and cardiovascular toxicity are the two most important safety concerns as well as potential drug interactions. Aspirin and selective serotonin reuptake inhibitors (SSRIs) for depression may significantly increase bleeding risk when co-prescribed with NSAIDs.

Current NICE Guidance on the management of osteoarthritis (OA) and rheumatoid arthritis (RA) largely supports the evidence base and MHRA advice, with NSAIDs (including COX-2 Inhibitor) being considered only after alternative forms of intervention have been attempted. There is however no clear distinction made between preferential use of traditional NSAIDs compared with COX-2 selective inhibitors for people with pre-existing cardiovascular risk (as in RA) other than to take into consideration individual patient factors.[184,185]

NICE Recommendations for the management of OA and RA are summarised in Appendix 2.

3.3.2.4 Rationale for Inclusion of NSAID Use as Part of the Intervention

Despite repeated safety warnings and recommendations to consider carefully the use of NSAIDS (including COX-2 Inhibitors), as also summarised in the BNF, the number of prescriptions issued for these drugs remains extremely high.[186] Between April–June 2007, 4.3 million prescriptions for NSAIDs were issued with 45.9% being for diclofenac, 6% for coxibs and 8% for meloxicam and etodolac. Sheer volume of prescriptions for these drugs translates to an estimated 240 additional premature cardiovascular events in England alone with most being attributable to diclofenac.[174]

Even where authoritative guidance exists advising against their use, historically, many clinicians have not followed it indicating that significant barriers to incorporating research findings into practice remain.[174]

The rationale for including NSAID prescribing as a therapeutic topic was based on the fact that NSAIDs continue to be widely prescribed despite evidence-based recommendations to carefully consider the benefit versus risk profile in relation to individual patients.

The key messages underpinning the evidence base, to be delivered as part of the intervention therefore, relate to patient safety and the risks associated with NSAID use. The importance of assessing an individual's cardiovascular, gastrointestinal and other risk factors in order to make an appropriate prescribing choice in the context of an overall reduction in use of NSAIDs will be stressed.

Chapter 4

Methods

This section describes the basis of the study design and the rationale for the methodologies adopted. The data sources accessed for evaluation of the intervention are described.

4.1 Study Design

A randomised controlled trial (RCT) design is generally regarded as the gold standard and most robust means of evaluating the impact of a defined intervention.[63,64,187,188,189] Randomisation is the most robust method of preventing selection bias. For an exploratory trial it also enables assessment of the size effect and provides a more solid basis for calculating sample sizes for any larger trial.[63,64]

Ideally, a study design whereby practices are randomly allocated to intervention and non-intervention (control) groups would have been preferred. However, because of the small sample size and exploratory nature of this study, this was not feasible. Instead, a quasi-experimental design (also known as a pre-test, post-test design) was adopted whereby a control group was also identified for comparison.[189,190,191]

The most common and preferred (robust) design is a controlled before and after study where a control (business as usual) or non-intervention population is identified which has similar or the same characteristics to the study population.[189,190] Data are collected in both groups before and after implementation of the intervention. A comparative analysis is then performed between the groups and any observed differences assumed to be due to the intervention.

In order to analyse data from a pre-post test design, it is essential to collect quantitative outcome data. It is also important to collect multiple forms of data where possible. MRC guidance suggests involving different methodologies and combining evidence from a variety of sources in the evaluation of complex interventions.[64] In addition to the quantitative evaluation, the study also involves a qualitative component, in order to gain greater understanding of the implementation of the intervention in practice.

This study therefore involves a pre-test, post-test design comparing the intervention group with control group. A mixed methods approach, combining both quantitative and qualitative methodologies was adopted.

4.2 Mixed Methods Adopted in the Evaluation of the Intervention

4.2.1 Quantitative Evaluation of Prescribing Change

NHS prescribing information is available as ePACT (Prescribing Analysis and CosT) data. Data is uploaded monthly (six weeks after the dispensing month) following prescription returns from community pharmacists. ePACT.net is an application which allows nominated users in the NHS to electronically access prescription data. Its facility enables PCT prescribing advisers to access and analyse the previous sixty months prescribing data held on the NHS Prescription Services Prescribing Database. The data is used to measure and compare prescribing and is frequently shared openly between practices.[192]

Practice and GP prescribing data can be analysed and compared using a variety of patient denominators.[193] Prescribing data can also be weighted to take into account practice populations and demographics as well as therapeutic class of drugs. One such weighting is ADQ per ASTRO-PU (Average Daily Quantities weighted by ASTRO-PU) and is a preferred unit of measurement. ADQ is a measure of prescribing volume based upon prescribing behaviour. It is an analytical unit defined by the Prescribing Support Unit used to compare prescribing activity. ASTRO-PU (Age-Sex and Temporary Residence Originated Prescribing Unit) is a weighting which takes into consideration differing practice populations. STAR PUs (Specific Therapeutic group Age-sex weightings Related Prescribing Units) are an alternative weighting which, also takes into consideration usage of drugs in certain therapeutic classes. Where ADQs are not appropriate, items and cost-based denominators weighted by ASTRO-PUs or STAR-PUs also provide comparative data.

A tagging facility is available in ePACT, enabling specific or tailored information requests.[194] A set of predefined tags is available within ePACT. However, selection of data can also be tailored to the requirements of the user by setting up specific tags. Selection and download of data can be grouped by specific practices (e.g. rural, dispensing, locality) or according to specific BNF categories (e.g. practice formulary, specialist drugs). BNF tags can be shared between users to enable monitoring of defined data sets across a PCT or for use in other PCTs.

4.2.1.1 Pre-Post Intervention Evaluation - Prescribing Outcomes

The primary aim of the study is to determine whether prescribing support from prescribing advisers influences GP prescribing behaviour and promotes the uptake of evidence-based prescribing. The primary quantitative measure is intended to detect and evaluate any change in prescribing patterns following the intervention compared with baseline and to compare with non-intervention practices.

The main evaluation therefore assesses the impact on pre-defined prescribing indicators following delivery of the intervention compared with baseline. Data for the quarter following delivery of the intervention was compared with prescribing data for the quarter immediately preceding implementation of the intervention (baseline). The study was powered to detect statistically significant differences in defined prescribing measures between intervention and control groups.

4.2.1.2 Prescribing Trend Data

In addition to the quarter on quarter comparison, monthly prescribing data was also collated for each practice in order to detect any obvious differences in prescribing trends throughout the intervention period in the intervention practices compared with control practices. The data is presented in graphical format.

4.2.2 Quantitative Evaluation - Patient Outcomes

Evidence is lacking that interventions intended to change clinical behaviour improve outcomes for patients or improve patient care.[54] Therefore, a separate quantitative pre-test post-test evaluation was conducted in order to establish whether the intervention intended to improve GP prescribing had a corresponding effect on measurable patient-orientated outcomes.

This quantitative evaluation assesses the impact of the intervention on pre-defined patient related outcomes by assessing the difference in the proportion of patients meeting predefined audit standards both before and after implementation of the intervention. Patient-orientated outcomes were defined, based on indicators which are predicted to reflect the appropriate management of T2DM and musculoskeletal conditions. Specific clinical outcome measures (HbA1c, BP) were also included in this group of indicators.

Patient-related outcome data are only available through individual practice systems. It was not possible to access all control practices. However, a group of practices within the control group permitted access to their data which provided a benchmark by which to compare intervention practices. Practices in this sub-set of the control group are referred to as ‘benchmark’ practices for the purposes of this evaluation. Patient related outcome data was collated from all intervention practices and all benchmark group of practices both at baseline and then again following the intervention.

Key prescribing and patient orientated outcomes for each therapeutic topic and corresponding data sources are summarised in Appendix 3.

4.2.3 Qualitative Evaluation

4.2.3.1 Introduction

The purpose of the qualitative evaluation was to collect descriptive and contextual data in order to evaluate the experience and perspectives of participants at whom the intervention was targeted. It explores GP perceptions, attitudes and beliefs both before and after the intervention in order to provide greater insight to the intervention and its impact on behaviour in practice. It seeks feedback on delivery and acceptability of the intervention in influencing GP prescribing behaviour. The clinician perspective is also explored in terms of delivery of the intervention to improve uptake and incorporation of evidence into the clinical decision-making process.

Data collection for the qualitative evaluation was achieved through pre-intervention and post intervention semi-structured interviews with GPs in participating practices. Interviews were transcribed and analysed using accepted qualitative methodologies.

4.2.3.2 Methodological Approach

It is not possible to explore and provide a detailed review and evaluation of the various practical approaches or theoretical underpinnings of qualitative research in this section. Many standard texts exist for reference.[195,196,197] However, the main concepts, principles and rationale adopted in approach to the qualitative evaluation in this study are summarised briefly here.

Much qualitative analysis falls under the general heading of 'Thematic Analysis', in effect a 'generic' tool which is often adopted within different methods. It involves a series of stages including organising and indexing data, extracting and coding elements of the data, developing themes and categories and potentially progressing to further theoretical analysis.[198] Categories may be derived inductively that is, obtained from the data, or used deductively as a way of approaching the data.[199]

Grounded Theory, is one such methodology used and accepted in qualitative research.[200] The aim is to generate theory and a higher level of understanding that is 'grounded' in or derived from analysis of the data, rather than testing theory as in a positivist approach. It is inductive in nature although deductive elements may be incorporated in the analysis.[201,202,203] Individuals sharing common circumstances, experiencing common perceptions, thoughts and behaviours are also the essences of grounded theory and on which its epistemological underpinnings are based.[204]

In grounded theory, the analytical process begins during data collection, shaping ongoing data collection through an iterative process. Constant comparative methodology allows the researcher to further refine questions, and pursue emerging themes in more depth.[200,204]

There is a lack of evidence or existing theory regarding incorporation of evidence-based findings into clinical decision-making hence there is no preconceived theoretical perspective in this situation. Grounded theory was deemed an appropriate basis for this study in order to generate theory that addresses a conceptual area of enquiry around professional behaviour.[204]

4.2.3.3 Framework Analysis

Framework Analysis is a more recent approach to qualitative analysis, explicitly developed in the context of applied policy research. It shares many common features of much qualitative analysis, including 'thematic analysis'.[198]

The general approach to framework analysis remains inductive as in grounded theory. However, it also allows for the inclusion of 'a priori' as well as emergent concepts.[198] There are five key stages of Framework Analysis, familiarisation with the data, identifying the thematic framework, indexing, charting and mapping and interpretation.

There is no one right way to analyse qualitative data, however, it is important to describe the approach adopted in the analysis and its relevance to the methodology.[198,203,205,206] In this study, there were clearly aspects of the data which related to pre-existing aspects of local and national policy, as well as patient care.

Framework analysis was therefore deemed a relevant and suitable method of data analysis for this study. The principles of grounded theory however were incorporated in the methodology during data collection.

The methods adopted in data collection and analysis are described in Section 4.12.

4.3 Pharmacist Preparation and Training

One crucial component of the complex intervention being delivered in practices was the pharmacists themselves. In order to deliver the intervention as intended, it was necessary that they were equipped with the necessary skills, knowledge and expertise. All participating pharmacists were therefore required to meet at least NPC Level 2 competencies for pharmacists working in primary care. Key competencies included sound clinical therapeutic knowledge, excellent communication and interpersonal skills, knowledge of health policy and priorities and skills in the management of change as well as experience working in primary care with GPs.

All pharmacists involved in delivering the intervention were employed within the PCT with job role functions ranging between Band 8a and 8d as defined in the NHS Knowledge and Skills Framework.[207] All were fulfilling roles requiring clinical expertise with sound knowledge of prescribing, pharmacy and medicines management issues. All had experience working in primary care and with GPs.

It was desirable that each pharmacist should have a Postgraduate MSc/Diploma in clinical pharmacy or equivalent as part of their role specification. All pharmacists in the study had at least one postgraduate qualification. (Pharmacist details - Appendix 4).

Although all the pharmacists involved in the study, were operating at a relatively senior level and were experienced health care professionals, it was necessary, for the purposes of the study to ensure that all were equipped with an appropriate knowledge and skill set and which was consistent across the group. To this end, therapeutic update training and personal development training was commissioned for completion before delivery of the intervention in practices.

Pre-study preparation focussed on three areas:

- Information Mastery
- Therapeutic Updates
- Academic Detailing

Most if not all pharmacists had previously attended NPC training on Information Mastery, Diabetes and Non-steroidal Anti-inflammatory drugs. For the purposes of the study however, the pharmacists attended relevant NPC training updates. Bespoke training in academic detailing was provided by an independent training company.

4.3.1 Information Mastery

The NPC 'Information Mastery for Local Decision Makers' Workshop was commissioned and delivered by an NPC PlusTraining Adviser. All pharmacists involved in delivering the study intervention attended. The workshop was also open to members of the local prescribing sub-groups, interested GPs and to other members of the Medicines Management Team. NB: None of the GPs from practices subsequently involved in the study intervention attended the training.

The aim was to update participants with the necessary skills to adopt an evidence-based approach in practice and incorporate relevant information into clinical decision-making. The course plan and content were discussed and agreed between

the trainer and the chief investigator prior to the delivery, in order to tailor the content to the needs of the attendees, in particular the pharmacists.

The interactive workshop involved didactic sessions and small group workshops. It included techniques in accessing most recent and relevant information from trusted sources, how to interpret statistical data, determining robustness of clinical trials and critical appraisal of published studies.

4.3.2 Therapeutic Workshop - Type 2 Diabetes and NSAIDs

NPC Plus training was commissioned to provide updates for the pharmacists involved in the study on the therapeutic topics chosen as the focus for the study intervention. An NPC trainer/facilitator who had previously provided PCT training was contacted to discuss training requirements and the feasibility of bespoke therapeutics training to support the pharmacists delivering the study intervention.

The aim was to provide pharmacists delivering the intervention with updated therapeutics training focussing on T2DM and NSAIDs with relevant Information Mastery included. The workshop was also open to other members of MMT.

The course plan and content were discussed and agreed between the chief investigator and NPC Plus trainer, and the content tailored to attendee requirements of the, in particular the pharmacists. Copies of draft documents summarising the evidence and key messages for NSAIDs and T2DM prepared during ongoing development of the detail aids were provided to the trainer for information in advance of the training.

NSAIDs

Key messages and supporting evidence relating to NSAIDs focussed on managing risk as highlighted in Section 3.3.2.

T2DM

The focus in T2DM was on management of cardiovascular risk (BP, blood lipids and aspirin), newer drugs for the management of blood glucose, appropriate use of RAS drugs (for management of hypertension and diabetic nephropathy) and self-monitoring of blood glucose. Knowledge of and reference to original clinical studies providing the evidence to support the key messages was a crucial aspect of the therapeutics training.

The training was also tailored to consider academic detailing techniques and the use of detail aids in the delivery of key messages as an element of the intervention. To this end a dedicated session on action planning was included. This incorporated development and utilisation of a Detail Aid Matrix and use of the Detail Aid Matrix in selling key messages and influencing behaviour as part of the planned interactive meetings with GPs. (Refer to Section 4.4).

A comprehensive Lesson Plan was developed by the trainer which was agreed prior to implementation. (Appendix 5) The training session covering both therapeutic topics was delivered over one day. NPC Plus hand-outs reinforced the key messages and background references and resources for pharmacists to utilise if required when delivering the intervention visits.

4.3.3 Therapeutics Workshop – Renin-Angiotensin Drugs

Management of renal disease (using RAS drugs) is an important aspect of management of T2DM. Prior to the intervention, a free NPC workshop on Renin-Angiotensin System (RAS) Drugs was offered and therefore commissioned to supplement the evidence-based therapeutics training (relating to T2DM) for pharmacists delivering the study intervention. Other members of MMT and local primary care clinicians were invited to attend.

Appropriate prescribing of RAS drugs is a national QIPP (Quality, Innovation, Productivity and Prevention) agenda Medicines Management option for local implementation. Despite the evidence base and policy approach, there continues to be a relatively high use of A-II-As in preference to ACE-Is.

The RAS drug update session covered factors guiding the evidence-based practice approach influencing choice of RAS drug, therapeutic dilemmas and a review of local prescribing patterns from ePACT data.

The pharmacist training, aims, learning objectives and expected outcomes for the Information Mastery training and the therapeutic updates (T2DM, NSAIDs and RAS drugs) are summarised in Appendix 6.

4.4 Provision and Development of Academic Detailing Training and Aids

The pharmacists involved in delivery of the intervention, by virtue of their existing roles and competencies, arguably already exhibited skills in influencing behaviour change and in implementing academic detailing techniques. However, the majority had not previously been introduced to the concept of academic detailing or received formal training in the approach. Bespoke training was therefore commissioned to ensure that they were familiar with the principles of academic detailing and able to conduct educational outreach visits using relevant skills in order to facilitate change in prescribing behaviour.

Investigation revealed that NHS training dedicated to academic detailing was lacking and that little commercially available training was available at the time including from the NPC (other than the dedicated session included in the therapeutic training workshop). Other options to access bespoke detail training were therefore explored.

The company commissioned to provide academic detailing training, (Focus Games Ltd.) was recommended by the acting Chief Pharmacist in a neighbouring PCT (an independent Healthcare Consultant with experience in both the pharmaceutical industry and the NHS). It describes itself as 'a clinical engagement, benefits realisation and change management consultancy specialising in front line communication work primarily within the healthcare sector'. It had experience of working with the Department of Health, the Pharmaceutical Industry and in delivering clinical engagement programmes within the NHS.

The course leaders had practical experience of drug detailing and communication techniques and in pharmaceutical marketing and training involving provision of detail training for outreach visits as well as development of communication skills. They had clinical (nursing) background qualifications.

4.4.1 Development of Academic Detailing Training

Several meetings were held between the Chief Investigator and the Company to discuss and finalise the training. Discussions focussed on development of a training package to meet the requirements for delivering the study intervention and establishing that the trainer would be able to meet the required objectives.

Training was developed on the understanding that the academic detailing approach was part of a complex intervention based on practice visits, which involved engaging the group in discussion about specific therapeutic topics using detail aids, incorporating presentation and feedback on prescribing data, additional written support material, and implementation of agreed actions.

The training addressed development and utilisation of structured Detail Aids which were evidence-based, focussing on the key messages to be delivered and reinforced by the pharmacists during practice visits. Draft study detail aids were utilised during training as the focus of exercises on detail aid development and building the detail "story board". This approach also enabled the pharmacists to familiarise themselves with the detail aids (and content), which were relevant to practice visits that they would be conducting. The emphasis on skills development, involved communication of the detail and key messages, agreement and quantification of actions with the GPs and applying pharmacists analytical skills in order to adapt to the visit dynamics.

The Aims and learning outcomes from the academic detail training are summarised in Appendix 7.

Two pre-workshop teleconference sessions were conducted plus pre-course work in developing an adoption ladder and question bank. Course activities involved identifying key messages, developing associated detail aids and using the adoption ladder and question bank in pre-prepared scenarios. The Detailing Skills Workshops ran over two consecutive days with a single day follow-up a week later. Funding was approved from the MMT training budget. Training approach, detailing skills principles and pre-course preparation are summarised in Appendix 8.

The training also provided opportunity to practice detailing techniques using pre-prepared vignettes. Role play sessions were included to enable pharmacists to practice under mentored conditions. Supplementary written training materials were also provided.

4.4.1.1 Academic Detailing Review Session

A separate review session was organised by the chief investigator for pharmacists delivering the study intervention, before baseline practice visits began, in order to ensure that they were clear on the visit objectives, intervention components and outcome measures as well as being familiar with the finalised detail aids, supporting slides and other materials including planning matrices and key reference documents. It also provided an opportunity to raise any outstanding queries.
A detailing skills presentation was included as revision and circulated to the pharmacists with a written summary of the session. (Appendix 9).

4.4.2 Detail Aids

Detail aids specific to the intervention therapeutic topics, required for delivery of the intervention were developed and prepared by the Chief Investigator. Examples of existing detail aids were sought for reference. A limited number of examples were obtained from the Northern and Yorkshire Regional Drug and Therapeutic Centre (NYDTC) Website, plus examples published in the NAO Report. A formal query to the UK Medicines Information Service (UKMI) identified no additional resources.

Key messages to be delivered within the intervention for each therapeutic topic were initially collated in summary documents in preparation for development of the detail aids. References supporting the evidence base were documented and potential points for discussion highlighted. (Appendix 10)

Trusted, validated evidence-based resources such as NICE and the NPC were accessed and utilised to distil the key messages for incorporation in the detail aids. (Appendix 11). The key evidence-based messages were integral to and consistent with the therapeutics update training organised for the purposes of the study. This approach ensured that detail aids were relevant and study specific.

Draft study detail aids were made available to academic detailing and therapeutics trainers for training purposes, and to support learning objectives relating to development of detail aids. A dual outcome was that key messages delivered by as part of the intervention were reinforced, and enabled the Pharmacists to practice detailing skills, using documents which would ultimately form part of the detailing package in practice.

The detail aids were prepared using Microsoft Office PowerPoint, presented in slide format. Key messages were distilled and supporting evidence based references included on the slides.

The NSAID and musculoskeletal pain detail aid consisted of twelve ‘slides’ The key messages targeted appropriate use and choice of NSAID, the importance of safety and minimisation of the clinical risk associated with individual drug choices. The main T2DM detail aid consisted of sixteen slides. The key messages targeted prioritisation of the multifaceted approach to management, reduction of cardiovascular risk and improving benefits for patients. The Detail Aids are included as Appendix 12.

Because T2DM is a long term condition and its management is complex and multifaceted, a set of (sixty) supporting slides was prepared in addition to the main detail aid. These focussed on specific aspects of management, highlighting key messages and the supporting evidence base within each topic. Its purpose was to provide further evidence for use by the pharmacists if required in tailored discussions during practice visits. (Appendix 13).

Additional slides were prepared during delivery of the intervention in response to queries, further topics raised during practice visits and in the light of new evidence.

4.4.3 Academic Detail Planning Matrix

A detail planning matrix is an extremely useful supporting tool for use when preparing delivery of an academic detailing session. The document is prepared

prospectively, enabling the person developing or delivering the detail to collate the relevant information to the key messages in one summary. It describes the aims of the detail, highlighting areas of controversy and identifies key supporting sources of information that the detailer should be familiar with before the visit.

The planning matrix template contains two elements which are completed as part of the detail development. One element focuses on, and lists the key messages to be delivered during the detailing session. Any important features associated with each key message are identified and any benefits associated with implementation are also listed. Credible sources of information which underpin each message are identified and suitable questions relating to each message are considered.

The second element of the planning matrix focuses on the main aims of the detailing session. Any known areas of controversy are documented. Mandatory literature or policies that the detailer requires and should be familiar with before the visit are listed. Possible opening questions to initiate discussion and to ascertain closure are documented and any support materials that the detailer should take with them are listed.

Completed Academic Planning Matrices (prepared by the Chief Investigator) for T2DM and NSAIDs using the planning matrix template from the NPC therapeutics update training session are attached as Appendices 14 and 15.

4.5 Study Approval

The research study received the following Research Ethics and Research Management and Governance approvals prior to commencement:

- Local (NHS) Research Ethical Approval – Cambridgeshire 4 Research Ethics Committee
- University of Bath, School for Health School Research Ethics Approval Panel
- PCT Research Management and Governance Approval - Peterborough and Cambridgeshire NHS Trusts (Primary Care)

4.6 Sample Size

Sample size calculations were based on the quantitative evaluation of retrospective prescribing data assessed over a twelve month period.

There was some uncertainty as to which prescribing indicator(s) would ultimately be 'primary' (as external factors may influence prescribing during the study). Some uncertainly also surrounded the sizes of effects that should be both worthwhile and achievable. Therefore, sample-size calculations proceeded by taking first a 'practical' sample-size -10 intervention and 10 control practices - and working out the consequences for power of that choice. Principal prescribing outcome measures were intended to include increase in metformin and reduction in total glitazones, reduction in diclofenac and reduction in overall NSAIDs.

Sample size calculations were carried out for these indicators using a two-tailed 5% level of significance for the effect of the intervention with 80% power. The variance estimates needed were obtained from regression analysis on the log scale of ePACT data for the financial quarter (July, August, September), 2008 on the corresponding data for 2007 for all 75 practices in NHS Cambridgeshire.

With 10 practices in the intervention group and 10 practices in the control group, this strategy would be able to detect a 10% increase in the prescribing of metformin, a 29% decrease in the prescribing of glitazones, 14% reduction in total NSAIDs and a 23% reduction in diclofenac.

Allowing for a 30% practice response rate and a potential further 10% loss of practices to follow up, 66 practices would need to be approached to participate in the study. As this is close to total number of practices in the PCT, all 75 practices were invited to participate.

4.7 Recruitment

The overall recruitment process for both the quantitative and qualitative elements of the study is summarised in the Recruitment Process Summary Flowchart. (Appendix 16).

4.7.1 Practice Recruitment

A routine Medicines Management newsletter was utilised to raise awareness about the study. It was distributed approximately one month before letters of invitation were sent to practices inviting them to participate in the study. (Appendix 17)

A letter providing study details was then sent to each practice GP prescribing lead, Senior Partner and copied to the Practice Manager. Copies of the Study Information Sheet and Expression of Interest form containing the researcher contact details and reply slip were included. (Appendices 18,19) Duplicate details were also e-mailed direct to each prescribing lead and practice manager. Interested practices were invited to contact the chief investigator for further information and, if required, to request a visit from the researcher to discuss the study design and participation requirements. Several practices requested a visit from the chief investigator to discuss participation.

Practices which did not respond either to express an interest or to decline participation were sent a follow-up invitation letter approximately two months later. Non-responders to this letter were deemed not to wish to participate.

Participating practices were required to provide signed consent before practice visits could commence. The senior partner or designated deputy (eg practice GP prescribing lead) acted as signatory for consent on behalf of all GPs in the practice (Appendix 20).

4.7.2 Qualitative Interviews – GP Recruitment

4.7.2.1 Pre-Intervention

Where practices agreed to participate, a further letter was sent to the GP Prescribing lead, and copied to the Practice Manager. The Qualitative Evaluation Study Information Sheet was enclosed for dissemination to practice GPs. (Appendices 21,22) The purpose of this letter was to recruit interested GP volunteers to participate in pre-intervention semi-structured interviews.

4.7.2.2 Post-Intervention

Following implementation of the intervention and completion of the practice visits, Participating GP Prescribing Leads were e-mailed in order to recruit interested GP volunteers to participate in post-intervention semi-structured interviews. The Qualitative Evaluation Study Information Sheet was attached for dissemination to practice GPs.

GPs who expressed an interest and agreed to participate in pre- or post- study semi-structured interviews were required to provide signed consent, prior to participation. (Appendix 23)

All Study Information Sheets and Consent Forms were approved for use as part of the NRES Local Research Ethics Approval Process.

4.7.2.3 Follow Up Communication with GP Practices

Following completion of the pre-intervention and post-intervention semi-structured interviews, letters were sent to GP practice prescribing leads and to individual GPs who participated in interviews thanking them for their time and commitment to participation in the study. They were advised that feedback would be available to participating practices once analysis and reporting of the data was complete. (Appendix 24).

4.8 Allocation to Groups Strategy

Because of the small sample size and exploratory nature of this study, it was not feasible to randomise practices to intervention and control groups. Instead, as a quasi-experimental design was adopted, it was necessary to define the intervention group and matched control group.

Cambridgeshire PCT was formed in 2007 following reconfiguration of three smaller PCTs with differing demographic patterns. These were Huntingdonshire, (predominantly town and residential), Cambridge City (high professional and student populations) and East Cambridgeshire and Fenland (largely rural farming area).

Intervention Group

Practices which consented to participate in the study were automatically enrolled to receive the study intervention. This group constituted the intervention group (twelve practices).

Control Group

Prescribing (ePACT) data is available for all practices in the PCT. It was therefore possible to define a group of practices of similar size and demographics to the intervention group In order to obtain a matched control group (no intervention) of equal sample size to the intervention group for the purposes of prescribing data analysis and statistical evaluation and in order to enable prescribing comparisons between intervention and non-intervention practices.

In addition to participating (intervention) practices, a number of practices (for various reasons unable to commit to study participation), granted access to the chief investigator to collect patient outcome data. These practices constituted the benchmark group against which intervention group patient-orientated outcome data was compared.

The number of benchmark practices (seven) was less than the number of intervention practices (twelve). Nevertheless, it was believed that they would constitute a benchmark for comparison against which it would be possible to detect some differences in achievement of patient outcomes in intervention group practices.

The study control group therefore consisted of the seven benchmark practices plus five additional non-intervention practices. Intervention and Control groups were matched as closely as possible for practice population size, locality and demographics in order to provide two equal sized groups with similar characteristics to enable prescribing data comparison and statistical analysis. (Summarised in Section 5.1)

4.9 Practice Visits

4.9.1 Pharmacist Allocation

Each pharmacist prescribing adviser conducting intervention visits was allocated to several participating practices. Where possible, pharmacists were allocated to practices where they were already known to the GPs, or working within the locality, in order to capitalise on pre-existing relationships as a credible source of information.

4.9.2 Intervention Visits

The intervention was conducted over a twelve month period. Four practice visits were conducted with each practice. Practice nurses, and practice managers were also invited to attend.

- Academic detailing approach involved:
    - Face to face meetings, engaging the GPs in discussions focussing on pre-determined therapeutic topics.
    - Identification of needs and issues of participants and presentation of cohesive arguments backed up by referenced facts.
    - Re-enforcement of Key messages.
    - Visit Outcome - that GPs agree a course of action which would be followed up in future meetings.

- Baseline visit. The prescribing adviser introduced themselves and provided a brief summary of the study (and therapeutic topics) to participants. Baseline prescribing data containing anonymised comparative PCT practice prescribing data was presented for discussion.

- Follow-up visits. Three follow up visits were conducted approximately 3-4 months apart. Meeting agendas were based on the pre-determined therapeutic topics, previous discussions and agreed actions. Previous messages were reinforced, feedback on prescribing was provided with additional support materials.

4.9.3 Evidence-Based Prescribing Support

Detail Aids

The detail aids were prepared in three formats to allow for flexibility in individual pharmacist presentation style.

Each pharmacist received one individual A4 size presentation folder containing hard copy Detail Aids. Two A3 folders were prepared for shared use for pharmacists preferring to utilise larger copy detail aids during practice visits. Pharmacists were also issued with a USB memory stick loaded with the PowerPoint detail aids for individuals or practices preferring electronic presentation during practice visits.

During the course of the intervention, new and updated detail aids produced in response to queries and on availability of new evidence were prepared, disseminated and added to all relevant folders.

4.9.4 Prescribing Data for Practice Visits

4.9.4.1 Baseline Visits

Prior to conduct of the baseline visits, the previous 12 month data were downloaded from ePACT.net for each therapeutic topic:

- Drug Group BNF Chapter 6.1.2 Endocrine – Drugs used in Diabetes
- Drug Group BNF Chapter 10.1.1 Musculoskeletal - NSAIDs

Total Items, Total Cost and Total ADQ data for each practice and for the PCT at individual drug level were downloaded into an Excel spreadsheet.

In order to provide comparisons, percentage items, cost and ADQs were calculated for the drugs listed, to show prescribing of each drug as a proportion of total prescribing within each therapeutic group. Differences between individual practice data and the PCT mean were then calculated in order to demonstrate how the practice prescribing compared with PCT averages. Data comparing use of topical NSAIDs compared with oral NSAIDs was also presented at baseline.

Graphs (pie-charts) of percent prescription items for each practice compared with the PCT average were prepared. (Example in Appendix 25) The data was presented in tabular and graphical format for presentation to practices by the pharmacists during the baseline visits.

4.9.4.2 Follow Up Visits

Because there is approximately 6-8 weeks delay in ePACT data availability, updated baseline prescribing data was unavailable for the second scheduled practice visits.

When available, data for the quarter following baseline was downloaded to identify any obvious differences in individual practices compared with PCT averages. Data manipulation was performed as for baseline. Data summaries were presented as previously in tabular and graphical (pie chart) format for the pharmacists to highlight and discuss any changes during practice visits.

Throughout the intervention period, the Chief Investigator also downloaded and prepared data to demonstrate prescribing trends for NSAIDs and drugs used in T2DM. Prescribing data was updated prior to each practice visit and provided to the allocated pharmacist for discussion with the GPs. It was presented in tabular and graphical format. The purpose was to provide feedback for GPs, and to demonstrate any shifts in prescribing during the study period and to monitor prescribing patterns in relation to agreed practice actions. The trend data was incorporated into the 'Visit Summary' for follow-up visits three and four. (Section 4.9.5)

Hard copies of practice e-PACT data were prepared for each pharmacist. Original copies were filed electronically in dedicated MMT folders and were available for uploading on to the pharmacist USB sticks if that was their preference.

4.9.4.3 Additional Prescribing Data Requirements

Following practice visits, several practices required additional prescribing information to inform further discussion or in order to support achievement of agreed

actions. In such situations, the data was downloaded and prepared for presentation by the nominated practice pharmacist themselves (depending on their ePACT skills) or, by request for required data to the Chief Investigator.

Pharmacists allocated to practices were aware that the Chief Investigator had collected patient-orientated outcome data from practice searches. Baseline practice data (e.g. renal data) was also shared by the pharmacist with certain practices to further inform discussion and achievement of agreed actions.

4.9.5 Visit Summaries

Visit summaries were prepared by the Chief Investigator on behalf of the other pharmacists prior to the third and fourth practice visits for use during practice visits and for dissemination within the practice if required.

The report included most recent prescribing data for feedback to the practice with a written summary of any changes which had occurred since the previous visits and study start. Shifts in prescribing trends were highlighted and documented. It also incorporated a review of agreed actions from previous meetings and evidence of progress. In addition, possible areas for follow-up discussion or actions for the following meeting were highlighted.

The Visit Summary specifically served as a pre-visit discussion document for those pharmacists who wished to discuss the upcoming visit with Chief Investigator prior to each meeting. An example is included in Appendix 26.

4.9.6 Visit Support Materials

Various support materials were collated to support the pharmacists in conducting the practice visits and to facilitate easy access to study related documents including evidence-based reference materials.

Support materials were provided for the pharmacists in two resource ‘packages’. Individual study folders were prepared for each pharmacist containing core study documents for reference (Appendix 27).

Written evidence-based information summaries and core references supporting key messages were also collated, and disseminated to the pharmacists delivering the intervention. Additional copies of evidence-based summaries were also available for dissemination to GP practice participants.

A central repository containing all study related documents, key references and additional resources was also maintained by the Chief Investigator.

During the course of the study, the Chief Investigator continued horizon scanning and evaluating more recent publications which may have been relevant to the topics discussed during the practice visits. Any new evidence was circulated to the pharmacists and filed for shared access accordingly.

4.9.7 Visit Reports

Following each practice visit, it was the pharmacist's responsibility to summarise the meeting, documenting discussions and any agreed actions in a visit report. The visit report was sent to the practice GPs following each practice visit.

A template was shared and adopted by the pharmacists as the approach to recording study practice visits, meeting discussions and agreed actions. Aspects of the visit which were routinely documented included attendees, main discussion points, topics discussed, resources supplied, agreed actions and responsibilities and arrangements for the next meeting.

Pharmacists were requested to send visit reports back to the practices within two weeks of conducting the practice visit. Copies of the visit reports were sent to the Chief Investigator. (Example visit reports included as Appendix 28).

4.9.8 Study Folders

All documentation relating to practice visits was held electronically in a central study folder in the MMT computer system. In addition, a central repository containing individual practice study folders (hard copy) was maintained by the Chief Investigator in a dedicated study cabinet. The study folders contained copies of all documents relating to the study visits, filed in date order, maintained on file for reference. The study folders therefore contained copies of the visit reports, practice data, visit summary reports and examples of evidence based reference materials used during the practice visits.

4.9.9 Review of Baseline Visits

Following completion of all baseline visits, a formal meeting was held with the pharmacists to review and discuss the visit process, share experiences and raise any issues which may require further action.

The Chief Investigator prepared a summary of the agreed actions from the baseline visits in order to identify any consistent themes or queries and to ensure that the pharmacists were fully supported in achieving their own agreed actions (such as provision of additional ePACT data). The Agenda, Discussion Points and meeting summary are included in Appendix 29.

The meeting provided an opportunity to review the conduct of the study and ensure that the intervention was being delivered in a consistent manner according to the defined protocol procedures.

4.10 Data Evaluation

4.10.1 Prescribing Outcome Measures

The primary outcome measures defined for statistical analysis and which determine the power of the study are based on differences between pre-intervention (baseline) prescribing volume and post-intervention prescribing volume (following completion of the study visits) for the intervention group compared with the control group. Primary and secondary prescribing outcome measures are based on evaluation of ePACT data.

The primary outcome prescribing measures for T2DM are based on an increase in prescribing of metformin and overall reduction in prescribing of glitazones. Secondary outcome measures include potential effects of the intervention on overall diabetic drug use and use of newer drugs in diabetes. (Table 4.1)

Primary outcome prescribing measures for NSAIDs are based on a reduction in the prescribing of diclofenac (and COX-2 Inhibitors) and an overall reduction in prescribing of NSAIDs. Secondary prescribing outcome measures anticipated for NSAIDs are aimed to identify shifts towards prescribing of alternative medications (ibuprofen and naproxen) which are associated with lower cardiovascular risk than diclofenac and COX-2 Inhibitors. (Table 4.1)

Prescribing Outcome Measures are summarised in Table 4.1

Therapeutic Topic	**Prescribing Outcome Measure**
Diabetes	• Overall Antidiabetic Drug Usage (All hypoglycaemic agents,excludes insulin)
	• Metformin Usage
	• Glitazone Usage
	• Other Antidiabetic Drugs (Newer drugs in diabetes, GLP-1 agonists, DPP-4 Inhibitors)
NSAIDs	• Diclofenac Usage
	• COX-II Inhibitor Usage
	• Overall NSAIDs Usage
	• Naproxen Usage
	• Ibuprofen Usage

Table 4.1 Study Prescribing Outcome Measures

4.10.1.1 Prescribing Data – Plan of Analysis

The plan of analysis compares the level of pre-intervention prescribing from ePACT data in a quarter (as measured by ADQs per ASTRO-PUs) compared with the same quarter one year later, (post-intervention) for each of the defined outcome measures. The effect of the intervention on prescribing will be evaluated by testing the null hypothesis that no prescribing differences exist between the intervention and control groups for each of the prescribing outcome measures. Evidence for statistically significant differences will be sought.

Descriptive statistics will also be performed on the data in order to describe the sample characteristics and check for violation of the underlying statistical techniques applied in analysis of the data.

4.10.1.2 Prescribing Data Collection

Pre-intervention prescribing data (as measured by ADQ Usage Per Items based ASTRO-PUs), was accessed and downloaded from ePACT for the financial quarter immediately preceding implementation of the intervention (July, August, and September) and for the same post-intervention time period the following year to enable before and after comparison. (2nd Quarter 2010/2011 compared with 2nd Quarter 2011/2012).

Data was grouped, selected and downloaded for intervention group practices and control practices by setting up and applying separate tags for each study group. (Data was downloaded for individual practices and for NHS Cambridgeshire as a whole in case access was necessary for comparison or perusal at a later date).
NB: Creating Tags for Indicators – Refer to Section 4.2.1.

Prescribing data relating to each therapeutic topic was downloaded into separate Microsoft Excel spreadsheets for data manipulation and analysis. Data for each of the outcome measures was transferred to a separate sheet within in each workbook. The differences between pre-intervention prescribing volume and post-intervention prescribing volume were calculated for each prescribing measure (indicator) within Excel.

Data files were further prepared within Excel so that they could be directly imported in the appropriate format into the SPSS Statistics software package for statistical analysis (IBMs Statistical Package for the Social Sciences).[208]

SPSS Version 18 (downloaded from Bath University Secure Downloads) was utilised for statistical analysis of study prescribing data.

Methods

4.10.2 Prescribing Trend Data

In addition to collection and analysis of prescribing outcome data, (used to determine statistically significant differences between intervention and control practices), prescribing trend data over the study period was collated for all of the intervention practices, all 'control' practices and the PCT as a whole.

Data from 'control' practices (non-intervention) would reflect general or background trends in prescribing patterns (local or national) and would be used as a benchmark by which to compare intervention practice prescribing patterns over the study period.

The purpose was to identify and establish whether there were any demonstrable trends or shifts in the prescribing of drugs used in T2DM and musculoskeletal disorders which might be attributable to the intervention in the intervention practices during the study period by comparing with background prescribing patterns in non-intervention practices.

Monthly prescribing data was downloaded from ePACT for each of the individual drugs in the BNF Sections indicated below:[186]

- BNF Chapter 6, Endocrine System
  Section 6.1.2 Antidiabetic Drugs
  Sulphonylureas (6.1.2.1), Biguanides (6.1.2.2) and Other Antidiabetic Drugs(6.1.2.3)

- BNF Chapter 10, Musculoskeletal and Joint Diseases
  Section 10.1.1 Non-steroidal anti-inflammatory drugs (including COX-Inhibitors)

4.10.2.1 Prescribing Trend Data Collection

Prescribing data, based on 'total items' for each drug prescribed each month in the defined BNF Sections was downloaded from ePACT for the twenty-one month period from April 2010 to December 2011. This time period therefore included approximately five months pre-baseline data and approximately four months post-study data.

Data was downloaded from ePACT and imported into a Microsoft Excel spreadsheet for further manipulation and analysis. Separate workbooks were used for intervention and benchmark practices and NHS Cambridgeshire. A separate work sheet was allocated for each practice.

Prescribing of each drug as a proportion of the monthly total items was then converted to a percentage figure, expressed as percentage of total items in the relevant BNF Section for that month.

Data manipulation involved further collation of figures so that certain classes or groups of drugs could be presented collectively (e.g sulphonylureas, COX-2 Inhibitors, combination products, 'Others'). Data was further manipulated within the spreadsheets so that overall prescribing trends could be presented graphically as demonstrated in the Results Section.

4.10.3 Practice Data - Patient Orientated Outcome Measures

4.10.3.1 Type 2 Diabetes

Thirteen patient-orientated outcome measures for patients with T2DM were defined focusing on three areas. These were, clinical outcomes, (recommended targets), appropriate prescribing of medication in T2DM and renal care measures, as follows:

Type 2 Diabetes	**Patient Orientated Outcome Measure**
Recommended Target Measures	Proportion of patients achieving: • Blood pressure (≤ 140/80mmHg) • Blood lipids (TC ≤ 5mmol/l) • HbA1c (≤ 7.5%) • HbA1c (≤ 9.0%) • ACR (men <2.5mg/mmol, women <3.5mg/mmol)
Prescribing Measures	• Proportion of patients on metformin, • Proportion of patients on lipid lowering therapy • Proportion of patients on aspirin • Proportion of patients prescribed a Renin-Angiotensin drug ○ Proportion of patients specifically prescribed an ACE-Inhibitor
Renal Care Measures	• Proportion of patients tested for microalbuminuria • Proportion of patients with microalbuminuria on a RAS drug • Proportion of patients with microalbuminuria attaining recommended BP target (≤ 130/80mmHg)

Table 4.2 Patient-Oriented Outcome Measures T2DM

4.10.3.2 Non-Steroidal Anti-inflammatory Drugs

Six patient-orientated outcome measures for patients on NSAIDs were defined focusing on three areas These were prescribing of NSAIDS in patients with clinical risk factors, concomitant prescribing of 'other' drugs (including drugs which increase GI risk and those which provide gastro-protection) and general prescribing of NSAIDs, as follows:

NSAIDs	Patient Orientated Outcome Measure

Risk Factor Measures	• Proportion of elderly patients (≥65) on NSAID
	• Proportion of patients with documented clinical risk factors (combined)
	  ○ Cardiovascular risk factors
	  ○ Gastrointestinal risk factors
	  ○ Cardio-renal Risk factors

Concomitant Medication Measures	• Proportion of patients on concomitant drugs
	  ○ Aspirin
	  ○ SSRI
	  ○ PPI (gastro-protection)

NSAIDs Prescribing Measures	• Proportion of patients on NSAIDs ○ NSAIDs (overall) as proportion of practice patient population

Table 4.3 Patient-Oriented Outcome Measures NSAIDs

4.10.3.3 Patient-Orientated Outcome Data - Plan of Analysis

Practice outcome data was subjected to two separate analyses.

4.10.3.3.1 Statistical Analysis

The main statistical evaluation of the intervention on which the power of the study is calculated is based on evaluation of prescribing data and comparison between intervention and control groups. However, the effect of the intervention on defined patient-oriented outcomes will also be evaluated by performing an analysis on the patient outcome data to establish whether a statistically significant difference in patient outcomes exists between the intervention and benchmark groups.

This statistical analysis will test the null hypothesis that no differences exist between the intervention and benchmark groups for each of the prescribing outcome measures. Evidence for statistically significant differences will be sought.

4.10.3.3.2 Comparison between Intervention and Benchmark Group Practices

Patient outcome data will also be reviewed and presented at individual practice level. This analysis will establish whether any obvious differences exist in achievement of outcome measures between intervention and benchmark practices.

For patients with T2DM, the plan of analysis compares proportion of patients achieving recommended treatment targets and receiving appropriate medication in the management of T2DM post-intervention compared with pre-intervention figures for each of the defined outcome measures.

For patients on oral NSAIDs, the plan of analysis compares proportion of patients with concomitant clinical risk factors or medication which may increase (or reduce) patient risk post-intervention compared with pre-intervention figures. Comparisons between pre-intervention and post-intervention proportions of patients on NSAID medication will also be made.

4.11 Collection of Quantitative Patient Orientated Outcome Data

GP practices hold patient medical records and associated information on dedicated practice computer systems which are an integral part of GP practice. A variety of commercially available systems are available and utilised in practice. Although systems may vary in layout, functionality and additional features, all perform the same basic functions.

A large amount of information is held on practice computer systems, covering all aspects of patient care including prescribing and chronic disease management. It is possible to extract information from the practice system in order to audit, track and monitor changes in health outcomes. Read Codes are a coded thesaurus of clinical terms used to record data (such as diagnosis, investigations, medication) on clinical systems in the UK. Data extraction from GP practice systems is facilitated by the use of Read coded information, irrespective of the commercial computer system implemented in the practice.

4.11.1 Patient Orientated Outcome Data Collection

For the purposes of the study, patient-oriented measures were defined for the two patient populations, those with T2DM and patients on NSAIDs. Data was collected from intervention and control practices according to the predetermined outcomes as summarised in Table 4.2 and Table 4.3.

Data sets were collected from all twelve intervention practices and seven benchmark practices prior to implementation of the intervention and the data searches were repeated approximately twelve months later following completion of the intervention study visits.

The data sets collected for T2DM and NSAIDs are summarised in Appendix 30 and Appendix 31 respectively.

Practice Systems

Patient-orientated outcome data was collected from nineteen practices in total. Three different practice systems were employed by the Intervention practices. All benchmark practices utilised the EMIS LV system. A summary of Intervention and Benchmark practice systems is provided in Table 4.4.

	Number of Practices	
Practice System	**Intervention**	**Benchmark**
EMIS	7	7
System One	3	0
Torex (RepAid Software)	2	0
Total	**12**	**7**

Table 4.4 Practice System Summary

4.11.2 Practice Data Collection Strategy

Building up each practice search requires a methodical and stepwise approach. Data collection was performed by employing the appropriate search strategy applicable to each practice system in order to achieve the specified data set.

Despite the differences in practice systems, it is possible to collect consistent data sets from each practice.

It was necessary at the outset to establish the overall practice population and calculate disease prevalence (proportion of patients with T2DM and proportion of patients on NSAID) both before and after the intervention in order to account for any possible increase or decrease in the study populations and in order to calculate pre-intervention and post-intervention differences.

It was also necessary to ensure that no major unanticipated changes in practice population had occurred during the intervention period. Otherwise, the figures may have required further adjustment in order to perform the required assessments.

Most practices utilised the EMIS-LV system. All Baseline and Post-intervention EMIS practice searches were performed by the chief investigator.
The EMIS search methodology and subsequent preparation of the Excel spreadsheets for T2DM data is described in Appendix 32. The EMIS search strategy and data collection process for NSAIDs is summarised in Appendix 33.

Baseline searches in System One practices were performed by the chief investigator with support from a pharmacy technician experienced in using the System One clinical system, to ensure that the required data set was collected. Post intervention searches which were essentially re-runs of the baseline searches were performed by the Chief Investigator twelve months later.

Practices using the Torex system also employ RepAid software which facilitates downloading of data according to the defined search strategy. The Torex system is not used widely in the PCT. The Torex searches were therefore performed in one of the intervention practices with support from the practice manager who had considerable IT experience to ensure that the required data set was collected. These searches were copied onto an encrypted memory stick in order to repeat the exact searches in the other participating Torex study practice and so ensuring consistent data collection.

In all cases, once the search had been performed, the resulting report was downloaded into a Microsoft Excel spreadsheet. Each Excel spread sheet was tidied, and each column was given an appropriate title labelling the data in it.

It was extremely important at this stage, and whilst still in the practice, to check that all of the columns had data entered (if available) as some practices may use different Read Codes or different descriptors (terms) for the same parameter. If there were differences, it was necessary to amend the report using the relevant Read Code or descriptors used by the practice and rerun the report and re-export the data into Excel. The file was then saved as an Excel workbook and filed on the practice system in appropriate folders. The spreadsheets were then forwarded for storage and analysis using a secure route via an nhs.net e-mail account and were also backed up on an encrypted memory stick.

Examples of the search outputs for each system are summarised in Appendix 34.

4.11.3 Analysis of Patient-Orientated Outcome Data

The tidied Excel spread sheets required further adaptation and manipulation prior to analysis to ensure that presentation of data sets were consistent between each practice and each practice system. Superfluous exported data was deleted (for example where systolic blood pressure and diastolic blood pressure values have duplicated date columns, one requires deletion).

NB: Missing Data. Where individual values were missing from exported data, calculations were still based on total practice population as a missing value was regarded as non-achievement of the target.

The data analysis was an intensive process requiring exploration and extraction of the information in each spreadsheet. A data recording form was prepared for each therapeutic topic in order to record the main results from the Excel data manipulation and to facilitate further analysis and reporting. (Appendix 35).

The summary data for each practice was further analysed within Excel and presented as a Data Collection and Analysis Summary for each therapeutic topic.

4.11.3.1 Statistical Data Analysis

The differences between the proportions of patients achieving pre-intervention patient outcome measures compared with proportions of patients achieving post-intervention outcome measures were calculated for each patient-orientated measure (indicator) within Excel.

Data files were further prepared within Excel so that they could be directly imported in the appropriate format into the SPSS Statistics software package for statistical analysis (IBMs Statistical Package for the Social Sciences).[208]

SPSS Version 18 was utilised for statistical analysis of patient outcome data.

4.11.3.2 Comparison between Intervention and Benchmark Group Practices

The purpose of the additional analysis was to determine whether it was possible to detect any obvious differences in patient-orientated outcomes between practices which had participated in the study and received the intervention, compared with non-intervention practices.

Data is presented in tabular form and key findings summarised in Section 5.4.2.

4.12 Qualitative Evaluation

Semi-structured in-depth interviews were conducted in order to obtain rich data. GPs from participating practices were invited to take part in semi-structured interviews both before and after implementation of the intervention to explore their perception of and attitudes towards the delivery and acceptability of the intervention and their perspective on the intervention to improve uptake and incorporation of evidence into the clinical decision-making process.

4.12.1 Sampling

Purposeful sampling was employed. The main inclusion criterion was that GPs from participating practices were willing to participate. Participating GPs represented a balanced sample from a range of practices. At least one, in some cases two GPs from each practice participated in a semi-structured interview.

4.12.2 Semi-Structured Interviews

Interviews were audio-taped and subsequently transcribed. Signed consent was obtained from GPs in order to tape record the interview and for permission to quote anonymised excerpts of transcripts in any potential publications or presentations arising from the study.

Seven pre-intervention semi-structured interviews lasting up to one hour were conducted with GPs in their practice base according to a pre-determined topic guide. (Appendix 36) Pre-intervention interviews were conducted using a Philips analogue recording device (Pocket Memo 381) and transcription equipment. Interview tapes were stored securely in a locked cabinet.

Thirteen post-intervention interviews were conducted with GPs in their practice base according to a pre-determined topic guide. (Appendix 37) GPs participating in post-intervention interviews had to have attended most if not all of the practice intervention meetings. Post-intervention interviews were recorded using an Olympus Digital Voice Recorder (DS-5000) and transcription device.

Each participant was identified by a pseudonym in order to maintain anonymity and confidentiality. Interview tapes and transcripts were identified by code so that participants were not identifiable from the transcripts. Interview tapes were destroyed once the data had been transcribed and verified.

4.12.2 Qualitative Evaluation – Data Analysis

Transcriptions were read whilst listening to the tape recordings and re-read before coding in order to become thoroughly familiar with the data. Data was then coded and grouped into concepts and further categorised to explore key themes arising from the interviews, in order to generate theory from the data. Constant comparative analysis was employed to compare emerging categories enabling further exploration of emerging themes.

Inter-Rater Reliability

Transcripts of one pre-intervention and two post-intervention interviews were also coded and emergent themes identified by two independent individuals experienced in qualitative research methodologies, in order to ensure validity and reliability of the thematic analysis as conducted by the researcher for all interview transcripts.

Chapter 5

Results Quantitative Evaluation

5.1 Recruitment

All seventy-five practices within the PCT were invited to participate in the study. Sixty-three practices responded to the letters of invitation (84% response rate). Twelve practices (16%) elected to participate in the study. Forty-one practices (55%) declined.

Details of the intervention and control practice populations and their localities are summarised in Table 5.1.

Summary - Practice Populations, Location and PCT Locality

Intervention Group			**Control Group**		
	**** Practice Population**	**Location**		**** Practice Population**	**Location**
CH Surgery	13,942	Town	CH Centre	13,662	Town
SE Centre	11,758	Town	BU Surgery	7,868	Rural^
SG Surgery	3,124	Rural^	OR Surgery	4,325	Town^
PH Surgery	4,504	Rural^	MK Centre	6,276	Rural^
PF Surgery	10,713	Town	RH Centre*	7,492	Rural^
WS Surgery	6,740	Rural^	WL Surgery*	7,074	City Centre
RH Surgery	15,349	City Centre	SY Surgery*	9,238	City Centre
TS Surgery	10,998	City Centre	CH Surgery*	10,646	City Centre
CM Centre	9,008	Rural	SM Surgery*	15,054	Rural/Town^
DM Centre	3,495	Rural^	PF Surgery*	5,794	Rural^
HJ Centre	8,246	Rural/Town^	BW Surgery*	7,883	Rural^
SM Centre	18,488	Rural/Town^	BN Surgery	18,048	Rural/Town^
Total	**116,365**		**Total**	**113,360**	

Key: * Benchmark Practice (Outcome Data)

Practice Locality: Huntingdonshire; Cambridge City; East Cambs and Fenland

* Benchmark practices for comparison of patient orientated outcomes data
** Practice Population Figures from August 2011
^ Dispensing Practice

Table 5.1 Practice Profile Summary

Details of Practice computer systems for Intervention and Benchmark practices are summarised in Table 5.2.

Allocation of Practice Pharmacists is summarised in Table 5.3

Summary – Practice Computer Systems (Intervention and Benchmark)					
Intervention Group			**Control Group**		
	Practice System			**Practice System**	
CH Surgery	EMIS-LV		CH Centre		
SE Centre	EMIS-LV		BU Surgery		
SG Surgery	EMIS-LV		OR Surgery		
PH Surgery	EMIS-LV		MK Centre		
PF Surgery	EMIS-LV		RH Centre*	EMIS-LV	
WS Surgery	Torex (Rep-Aid)		WL Surgery*	EMIS-LV	
RH Surgery	EMIS-LV		SY Surgery*	EMIS-LV	
TS Surgery	System One		CH Surgery*	EMIS-LV	
CM Centre	System One		SM Surgery*	EMIS-LV	
DM Centre	System One		PF Surgery*	EMIS-LV	
HJ Centre	EMIS-LV		BW Surgery*	EMIS-LV	
SM Centre	Torex (Rep-Aid)		BN Surgery		
Key:	* Benchmark Practice - Outcome Data				
Practice Locality:		Huntingdonshire			
		Cambridge City			
		East Cambs and Fenland			

* Benchmark practices for comparison of patient orientated outcomes data

Table 5.2 Practice Computer System Summary

Summary – Practice Allocated Pharmacists Intervention Group		
	Practice Pharmacist	
CH Surgery	Pharmacist 5	
SE Centre	Pharmacist 2	
SG Surgery	Pharmacist 5	
PH Surgery	Pharmacist 3	
PF Surgery	Pharmacist 2	
WS Surgery	Pharmacist 4	
RH Surgery	Pharmacist 4	
TS Surgery	Pharmacist 4	
CM Centre	Pharmacist 1	
DM Centre	Pharmacist 1	
HJ Centre	Pharmacist 1	
SM Centre	Pharmacist 2	
Practice Locality:		Huntingdonshire
		Cambridge City
		East Cambs and Fenland

Table 5.3 Practice Pharmacist Allocation Summary

5.2 Prescribing Data – Outcome Measures

5.2.1 Non-Steroidal Anti-Inflammatory Drugs

There were five NSAID prescribing outcome measures defined. These were difference in pre-intervention and post-intervention prescribing volume (as measured by ADQ per ASTRO-PUs) for the quarter (July, August, September), 2011 compared with the corresponding quarter 2010 for:

- Total NSAIDs
- Diclofenac
- COX-2 Inhibitors
- Ibuprofen
- Naproxen
- Ibuprofen and Naproxen combined

Descriptive Statistics

Summary descriptive statistics for the study sample (intervention and control) practices are summarised in Table 5.4. The Statistic values referenced represent the difference in prescribing volume (as measured by ADQ per ASTRO-PUs) between baseline value and post intervention value for each measure/indicator.

Descriptive Statistics									
Measure (Pre/Post Intervention Difference)	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**	**Skewness**		**Kurtosis**	
	Statistic Sample Size	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
NSAIDDiff	24	-83.3	8.3	-10.823	20.0271	-2.238	0.472	6.749	0.918
DicDiff	24	-76.6	5.2	-14.079	17.7234	-2.008	0.472	5.872	0.918
COXDiff	24	-6.4	2.9	-0.693	2.6223	-0.853	0.472	-0.377	0.918
IbuDiff	24	-10.2	11	-0.679	5.5472	0.393	0.472	0.004	0.918
NapDiff	24	-42	62.3	7.53	18.4541	0.287	0.472	4.314	0.918
IbNapDiff	24	-50.8	57.6	6.797	18.2739	-0.461	0.472	5.644	0.918

Table 5.4 Summary Descriptive Statistics - NSAIDs

More detailed summary statistics for each NSAID indicator are summarised in Appendix 38.

5.2.1.1 Testing for Significant Difference between Intervention and Control Groups

A number of assumptions are made about the population, from which the sample has been drawn when applying parametric techniques, including whether the data is normally distributed. Non-parametric techniques have less stringent assumptions and are often more suitable techniques for smaller samples or when the data is measured only at the ordinal (ranked) level.[209] It was therefore necessary to determine whether the data was normally distributed in order to apply an appropriate test for statistical significance.

5.2.1.1.1 Assessing Normality

Histogram plots were produced in order to assess the normality of distribution of the data for each measure (Appendix 38) Normal Q-Q Plots were reviewed in conjunction to assess deviation of the scores from the straight line. Box Plots were also produced for each measure enabling identification of specific outliers. Tests of normality were also produced as part of the data output.

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
Measure	Statistic	df	Sig.	Statistic	df	Sig.
NSAIDDiff	0.171	24	0.067	0.79	24	0
DicDiff	0.147	24	0.194	0.821	24	0.001
COXDiff	0.216	24	0.005	0.894	24	0.016
IbuDiff	0.127	24	0.200*	0.963	24	0.503
NapDiff	0.214	24	0.006	0.884	24	0.01
IbNapDiff	0.165	24	0.088	0.854	24	0.003

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

Table 5.5 Tests for Normality Summary for NSAID Prescribing Measures

Review of the histograms indicated that Overall NSAIDs, COX-2 Inhibitors, Ibuprofen Naproxen and Ibuprofen indicators may conform to normal distribution of the data. However, sample sizes were relatively small. Normality tests indicated that not all indicators were associated with normally distributed data. (Table 5.5)
NB: A non-significant result from normality tests (i.e.>0.05) indicates normality

Kolmogorov-Smirnov indicated that NSAIDs, Diclofenac Ibuprofen and Ibuprofen/Naproxen indicators may be normally distributed. However, Shapiro-Wilk Test (more appropriate for smaller sample sizes) indicated that the COX-2 Inhibitor indicator may be normally distributed.

It was therefore deemed appropriate to apply a non-parametric Mann-Whitney U test (used to test for differences between two independent groups on a continuous measure) to all NSAID indicators. Test statistics are summarised in Table 5.6

5.2.1.1.2 Mann-Whitney U Tests

Test Statistics[a]						
	NSAIDDiff	DicDiff	COXDiff	IbuDiff	NapDiff	IbNapDiff
Mann-Whitney U	39	34	26	67	46	37
Wilcoxon W	117	112	104	145	124	115
Z	-1.905	-2.194	-2.656	-0.289	-1.501	-2.021
Asymp. Sig. (2-tailed)	0.057	0.028	0.008	0.773	0.133	0.043
Exact Sig. [2*(1-tailed Sig.)]	.060[b]	.028[b]	.007[b]	.799[b]	.143[b]	.045[b]

a Grouping Variable: Group
b Not corrected for ties.

Table 5.6 Test Statistics Summary Mann-Whitney U Tests NSAID Prescribing Measures

	ADQ / ASTRO-PU Change – Intervention Practices (n=12)		ADQ / ASTRO-PU Change – Control Practices (n=12)		Mann-Whitney U Tests	
	Median	IQR	Median	IQR	Test Statistic	p-value
NSAID All	-13.1	17.8	-2.245	12.8	39	0.057
Diclofenac	-17.755	18.6	-2.13	14.3	34	0.028*
COX-2 Inhibitors	-0.56	4.4	1.145	1.5	26	0.008**
Ibuprofen	-0.95	7.4	-0.67	6.6	67	0.773
Naproxen	11.81	20.4	2.93	11	46	0.133
Ibuprofen/Naproxen	12.8	11.8	1.32	14.9	37	0.043*

* Significant at the 5% Level
** Significant at the 1% Level

Table 5.7 Statistical Significance Summary Mann-Whitney U Tests Prescribing Indicators

The results therefore indicate that statistically significant differences exist between intervention and control practices for the indicators diclofenac, COX-2 Inhibitors and combined ibuprofen and naproxen as summarised in Table 5.7 and as follows:

- Decrease in prescribing of diclofenac ($p<0.05$)
- Decrease in prescribing of COX-2 Inhibitors ($p<0.001$)
- Increase in prescribing of ibuprofen and naproxen (combined) ($p<0.05$)

Therefore, the null hypotheses that no difference exists in prescribing of diclofenac, COX-2 Inhibitors and naproxen plus ibuprofen between intervention and control groups are rejected.

5.2.1.2 Effect Size

The effect size (r) was calculated by using the reported value for z, where r = z / square root of N where N = total number of cases as summarised in Table 5.8. [210]

	r value	Calculated r value	Estimated Effect Size[208]
Diclofenac	r = -2.194/4.899	0.4478	Medium
COX-2 Inhibitors	r = -2.656/4.899	0.5422	Large
Ibuprofen and Naproxen	r = -2.021/4.899	0.4125	Medium

Table 5.8 Summary of Effect Size for Statistically Significant Values

5.2.1.3 Further Analysis

Outliers

It was noted that there were a limited number of outliers (cases with values well above or below the majority of other cases) for Total NSAIDs (Intervention Practice, 20), Diclofenac (Intervention Practice, 10), Ibuprofen (Control Practice, 01), Naproxen (Intervention Practices 10 and 20) and Ibuprofen/Naproxen (Intervention Practices 10 and 20). Refer to Appendix 38.

Outliers may affect the normality of the distribution and distort the statistics. It is possible to remove extreme outliers and adjust their value to a less extreme value so that the score does not distort the statistics. However, 5% trimmed mean values for all the indicators were similar to the actual means, indicating that the outliers were not distorting the statistics or causing a problem in terms of the analysis.

Nevertheless, it was decided to perform an additional analysis of the data excluding outliers to confirm statistical significance.

5.2.1.3.1 Tests of Normality

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
Measure	Statistic	df	Sig.	Statistic	df	Sig.
NSAIDDiff	0.144	23	.200*	0.931	23	0.117
DicDiff	0.13	23	.200*	0.944	23	0.224
COXDiff	0.216	24	0.005	0.894	24	0.016
IbuDiff	0.112	23	.200*	0.972	23	0.734
NapDiff	0.155	22	0.181	0.962	22	0.534
IbNapDiff	0.091	22	.200*	0.967	22	0.646

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

Table 5.9 Tests for Normality Summary Excluding Outliers - NSAIDs

Normality tests (Table 5.9) indicated that data for all indicators (excluding outliers) with the exception of COX-2 Inhibitors complied with a normal distribution. Therefore, an independent t-test (the parametric alternative to Mann-Whitney U test) was also performed for each measure.

5.2.1.3.2 Independent Samples T-tests

Independent Samples Test									
	Levene's Test for Equality of Variances		t-test for Equality of Means						
					p-value			95% Confidence Interval of the Difference	
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
NSAIDDiff	0.187	0.67	-1.424	21	0.169	-7.586	5.3277	-18.6655	3.4936
DicDiff	0.05	0.825	-2.139	21	0.044	-9.897	4.6278	-19.521	-0.273
COXDiff	1.759	0.198	-2.295	22	0.032	-2.2567	0.9832	-4.2957	-0.2176
IbuDiff	0.671	0.422	0.235	21	0.816	0.5092	2.165	-3.993	5.0115
NapDiff	0.109	0.744	1.986	20	0.061	8.4708	4.2643	-0.4244	17.366
IbNapDiff	2.035	0.169	2.559	20	0.019	8.9795	3.5084	1.6612	16.298

NB: Significance values for Levin's test for equality of variances are all > 0.05 indicating that variances for the two groups are the same.

Table 5.10 Statistical Significance Summary - Independent Tests for NSAID Prescribing Indicators

Results indicate that statistically significant differences exist between intervention and control practices for the indicators diclofenac, COX-2 Inhibitors and combined ibuprofen and naproxen as summarised in a Table 5.10 and as follows:

- Decrease in prescribing of diclofenac ($p<0.05$)
- Decrease in prescribing of COX-2 Inhibitors ($p<0.05$)
- Increase in prescribing of ibuprofen and naproxen (combined) ($p<0.05$)

Therefore, the null hypotheses that no difference exists in prescribing of diclofenac, COX-2 Inhibitors and naproxen plus ibuprofen between intervention and control groups are rejected. The results therefore support the conclusions from non-parametric tests on the individual outcome measures.

5.2.2 Type 2 Diabetes

There were four T2DM prescribing outcome measures defined. These were difference in pre-intervention and post-intervention prescribing volume (as measured by ADQ per ASTRO-PUs) for the quarter (July, August, September), 2011 compared with the corresponding quarter 2010 for:

- Total drugs in T2DM
- Metformin
- Total Glitazones
- 'Other' (newer drugs) in T2DM.

Summary descriptive statistics for the study sample (intervention and control) practices are summarised in Table 5.11 The Statistic values referenced represent the difference in prescribing volume (as measured by ADQ per ASTRO-PUs) between the baseline value and post intervention value for each indicator/measure

Descriptive Statistics									
Measure (Pre/Post Intervention Difference)	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**	**Skewness**		**Kurtosis**	
	Statistic Sample Size	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
AllDiff	24	-157.6	26.8	-1.303	35.8153	-3.893	0.472	17.105	0.918
MetDiff	24	-87.8	27.5	8.977	21.7448	-4.128	0.472	18.772	0.918
GlitDiff	24	-19.5	6.7	-8.28	7.1058	0.257	0.472	-0.274	0.918
OtherDiff	24	-16.4	5.8	0.928	4.1143	-3.365	0.472	14.38	0.918

Table 5.11 Summary Descriptive Statistics – Type 2 Diabetes

More detailed summary statistics for each T2DM indicator are summarised in Appendix 39.

5.2.2.1 Testing for Significant Difference between Intervention and Control Groups

5.2.2.1.1 Assessing Normality

Histogram plots were produced in order to assess the normality of distribution of the data for each measure (Appendix 39). Normal Q-Q Plots were reviewed in conjunction to assess deviation of the scores from the straight line. Box Plots were also produced for each measure enabling identification of specific outliers. Tests of normality were also produced as part of the data output.

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
Measure	Statistic	df	Sig.	Statistic	df	Sig.
AllDiff	0.259	24	0	0.543	24	0
MetDiff	0.327	24	0	0.5	24	0
GlitDiff	0.096	24	.200*	0.966	24	0.571
OtherDiff	0.243	24	0.001	0.644	24	0

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

Table 5.12 Tests for Normality Summary for T2DM Prescribing Measures

Review of the histograms suggested that Overall (total) Drugs in T2DM, Metformin, and 'Other' Drugs indicators may conform to normal distribution of the data. However, sample sizes were relatively small. Normality tests indicated that only glitazones were associated with normally distributed data. (Table 5.12)
NB: A non-significant result from the normality tests (i.e.>0.05) indicates normality.

It was therefore decided to apply non-parametric Mann-Whitney U tests (used to test for differences between two independent groups on a continuous measure) to all T2DM prescribing indicators. Test statistics are summarised in Table 5.13.

5.2.2.1.2 Mann-Whitney U Tests

Test Statistics[a]				
	AllDiff	MetDiff	GlitDiff	OtherDiff
Mann-Whitney U	56	69	55	68
Wilcoxon W	134	147	133	146
Z	-0.924	-0.173	-0.981	-0.231
Asymp. Sig. (2-tailed)	0.356	0.862	0.326	0.817
Exact Sig. [2*(1-tailed Sig.)]	.378[b]	.887[b]	.347[b]	.843[b]

a Grouping Variable: Group
b Not corrected for ties.

Table 5.13 Test Statistics Summary Drugs in T2DM Mann-Whitney U Tests

	ADQ Change - Intervention Practices (n=12)		ADQ Change - Control Practices (n=12)		Mann-Whitney U Tests	
	Median	IQR	Median	IQR	Test Statistic	p-value
T2DM All	1.1775	33.7	10.605	10.4	56	0.356
Metformin	14.86	11.1	12.655	9.7	69	0.862
Glitazones	-10.12	11.6	-6.985	6.7	55	0.326
Other	1.755	2.1	1.325	3.1	68	0.817

* Significant at the 5% Level
** Significant at the 1% Level

Table 5.14 Statistical Significance Summary Mann-Whitney U Tests Prescribing Indicators

The results therefore indicate that no statistically significant differences exist between intervention and control practices for the indicators Total drugs in diabetes, Metformin, Total glitazones or 'Other' drugs in T2DM. (Table 5.14)

Therefore, the null hypotheses that no difference exists in prescribing of Total drugs in T2DM, Metformin, Total glitazones and 'Other' drugs in T2DM, between intervention and control groups is retained.

5.2.2.2 Further Analysis

Outliers

It was noted that for all the indicators (except for glitazones, where tests had suggested normal distribution) there was one intervention practice which appeared to be an outlier for each indicator (3, CMC). Refer to Appendix 39.

As indicated earlier, outliers may affect the normality of the distribution and distort the statistics. 5% trimmed mean values for all the indicators were relatively close in value to the actual means, indicating that the outliers were not distorting the statistics or causing a problem in terms of the analysis.

Nevertheless, it was decided to perform an additional analysis of the data excluding outliers for the one intervention practice.

5.2.2.2.1 Tests of Normality

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
Measure	Statistic	df	Sig.	Statistic	df	Sig.
AllDiff	0.161	23	0.125	0.942	23	0.195
MetDiff	0.096	23	.200*	0.97	23	0.682
GlitDiff	0.096	24	.200*	0.966	24	0.571
OtherDiff	0.113	23	.200*	0.971	23	0.703

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

Table 5.15 Tests for Normality Summary Excluding Outliers – T2DM

Normality tests suggested (Table 5.15) that data for all indicators (excluding outliers) complied with a normal distribution. Therefore, an independent t-test (the parametric alternative to Mann-Whitney U test) was also performed for each measure.

5.2.2.2.1 Independent Samples T-tests

Independent Samples Test									
	Levene's Test for Equality of Variances		t-test for Equality of Means						
					p-value			95% Confidence Interval of the Difference	
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
AllDiff	7.08	0.015	-0.956	14.1	0.355	-5.5548	5.8125	-18.0165	6.9069
MetDiff	0.004	0.951	-0.154	21	0.879	-0.4648	3.0252	-6.7561	5.8264
GlitDiff	0.721	0.405	-1.127	22	0.272	-3.2508	2.884	-9.2319	2.7303
OtherDiff	0.244	0.627	0.831	21	0.416	0.6552	0.7888	-0.9852	2.2955

NB: Significance values for Levin's test for equality of variances were > 0.05 for three indicators (metformin, glitazones and 'Other' i)ndicating that variances for the two groups are the same. Alternative t-value output figures from SPSS were therefore substituted for Total Drugs in T2DM (AllDiff).

Table 5.16 Statistical Significance Summary - Independent t-Tests for T2DM Prescribing Indicators

The results therefore indicate that no statistically significant differences exist between intervention and control practices for the indicators Total drugs in diabetes, Metformin, Total glitazones or 'Other' drugs in T2DM. (Table 5.16)

Therefore, the null hypotheses that no difference exists in prescribing of Total drugs in T2DM, Metformin, Total glitazones and 'Other' drugs in T2DM, between intervention and control groups is retained. The results therefore support the conclusions from non-parametric tests on the individual outcome measures.

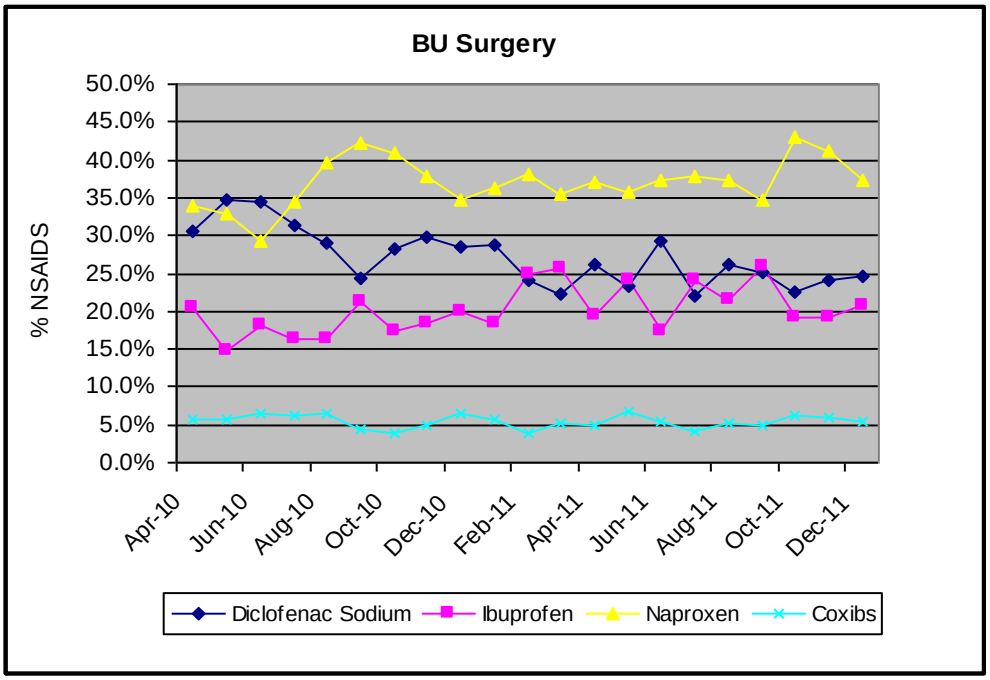
5.3 Prescribing Trend Data

This section consists of a series of graphs demonstrating prescribing trends in each practice for non-steroidal drugs and drugs used in diabetes throughout the study period. Prescribing trend data are presented for individual Control practices followed by Intervention practice data.

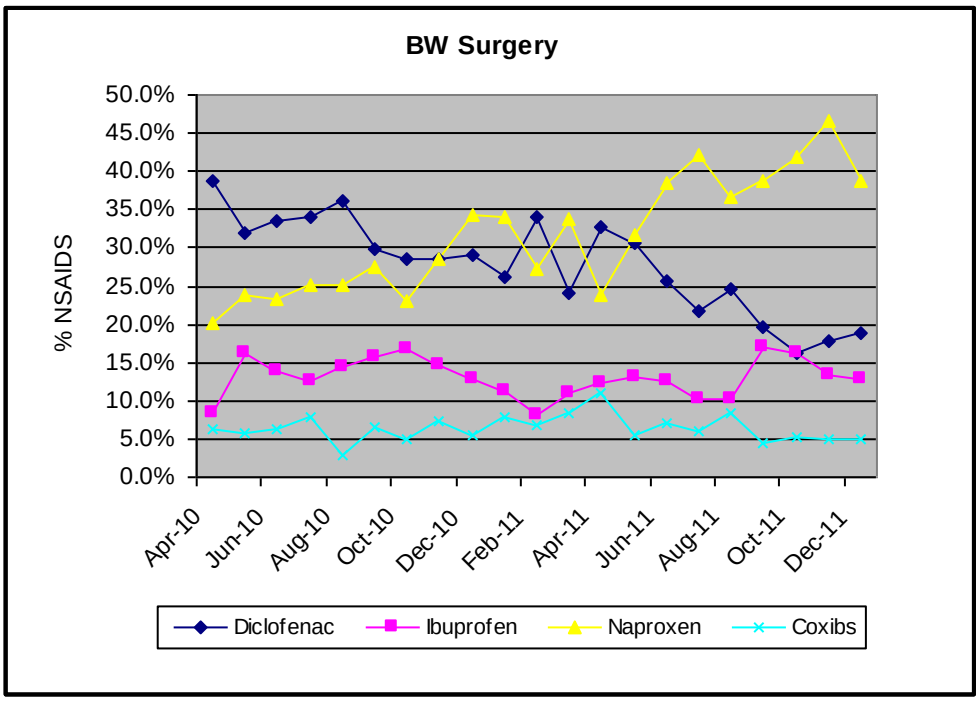
At the end of each section, aggregated data for specific NSAIDs and drugs used in T2DM are presented to enable overall comparisons between Intervention and Control practices.

5.3.1 Non-Steroidal Anti-inflammatory Drugs

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Control Practices

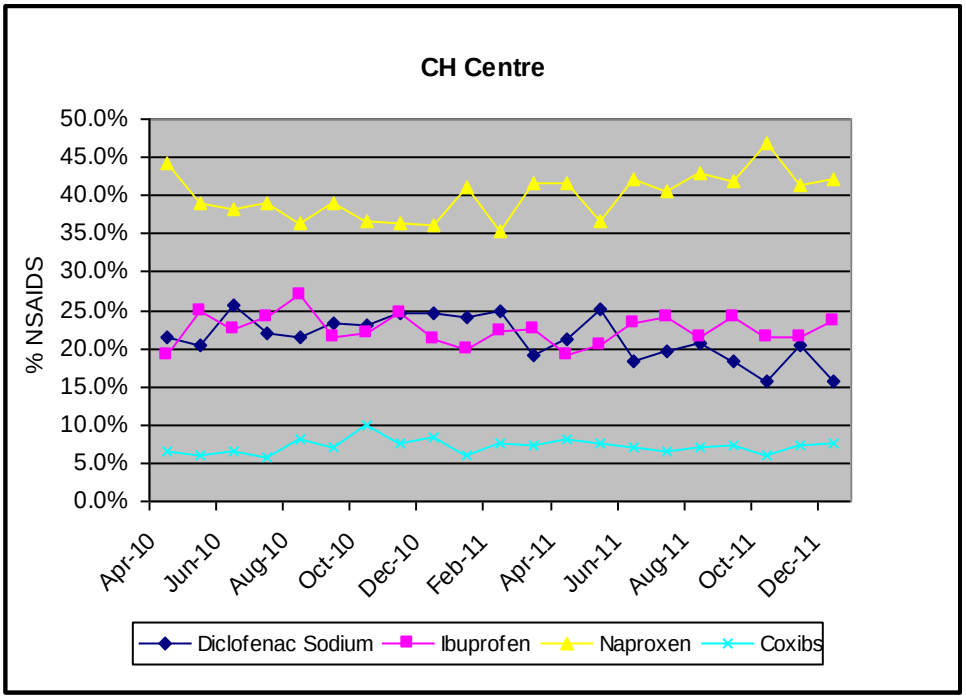


Graph 5.1. NSAIDs Trend Control Practice – BU Surgery

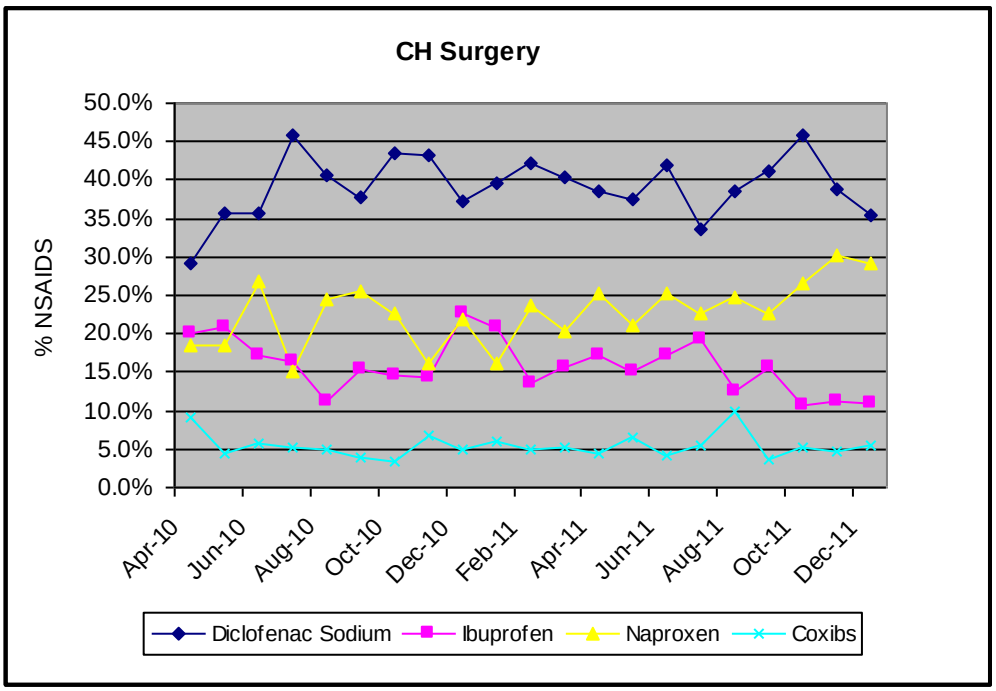


Graph 5.2. NSAIDs Trend Control Practice – BW Surgery

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Control Practices

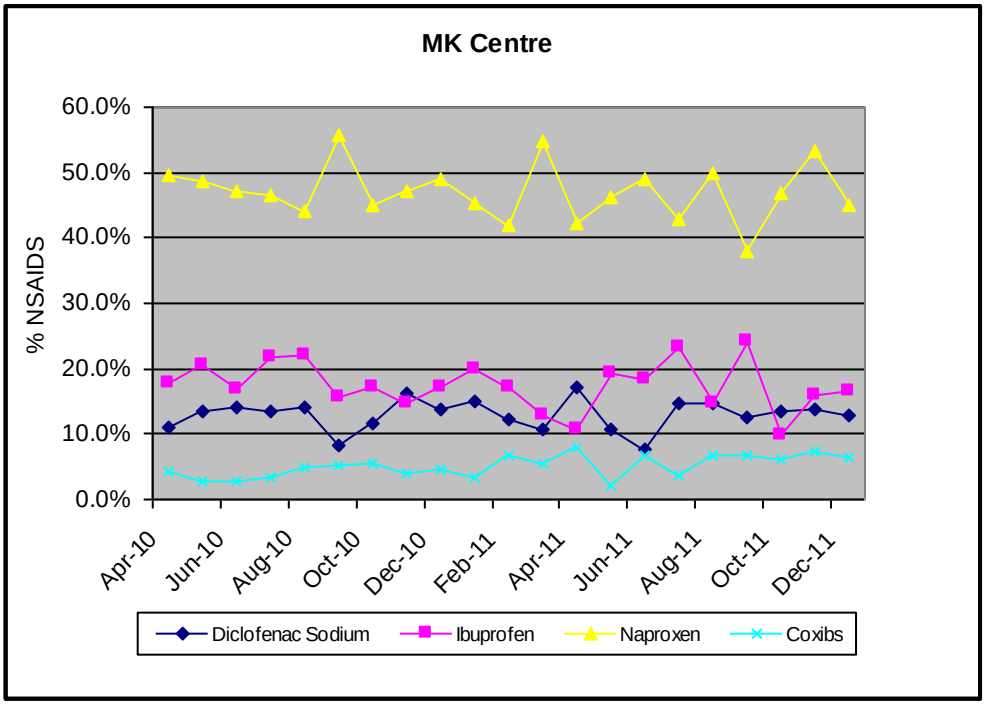


Graph 5.3. NSAIDs Trend Control Practice – CH Centre

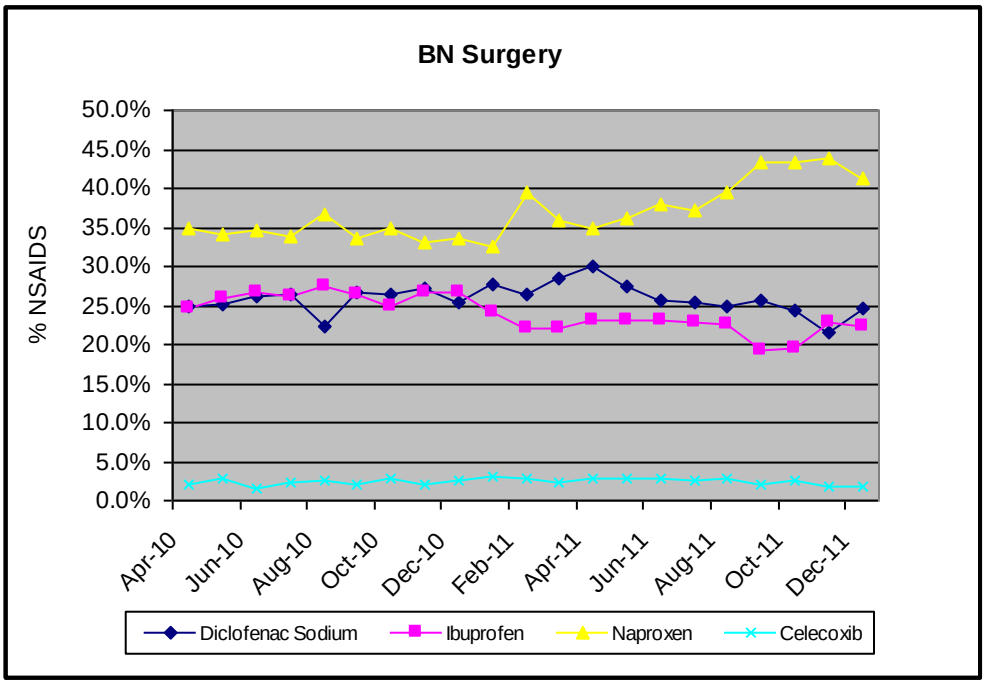


Graph 5.4. NSAIDs Trend Control Practice – CH Surgery

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Control Practices

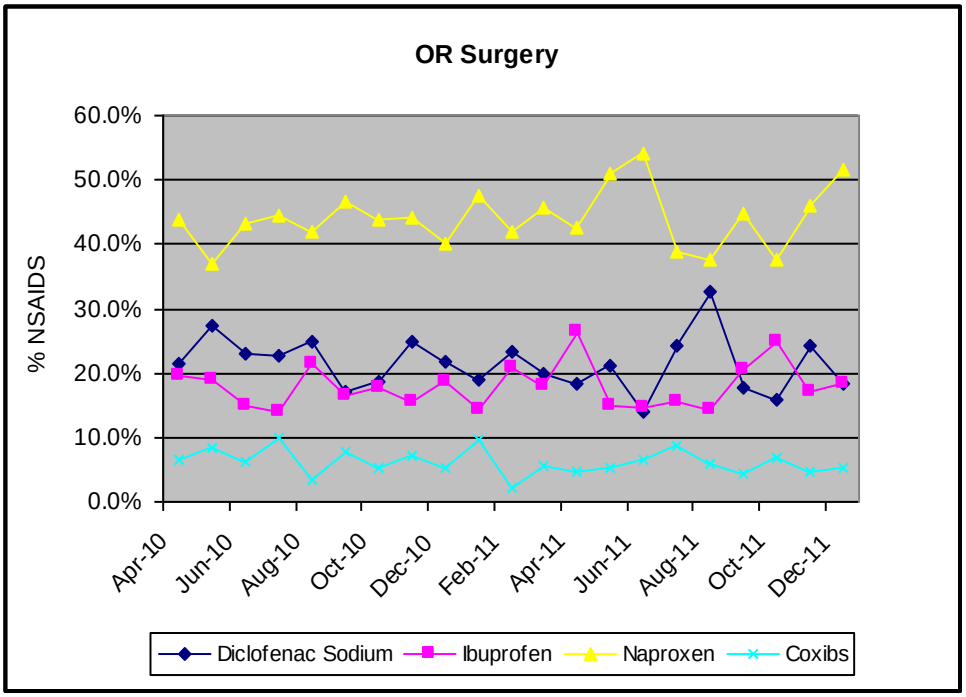


Graph 5.5. NSAIDs Trend Control Practice – MK Centre

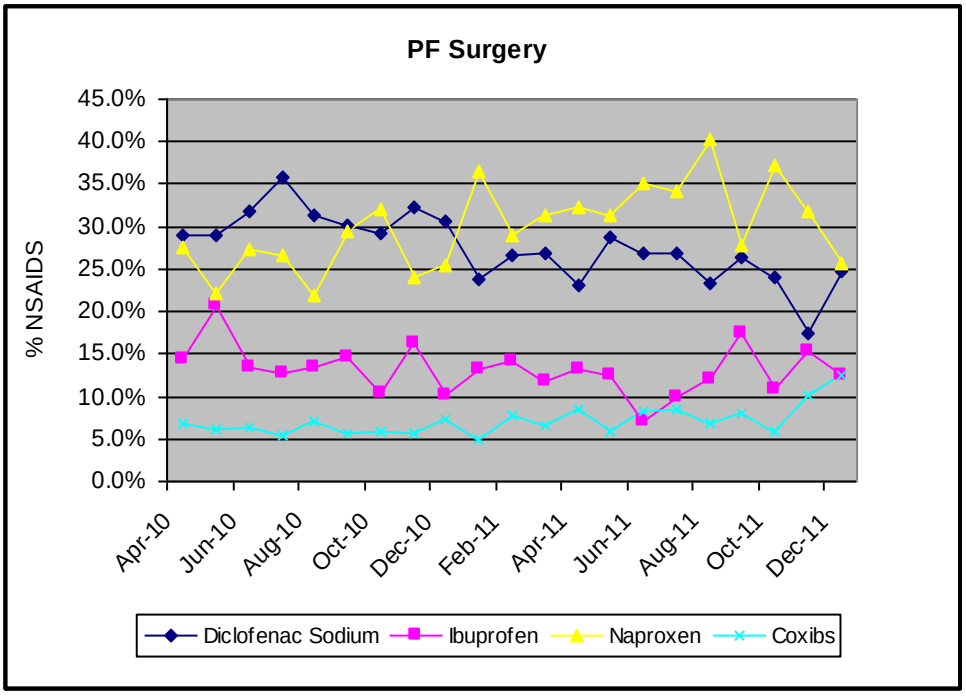


Graph 5.6. NSAIDs Trend Control Practice – BN Surgery

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Control Practices

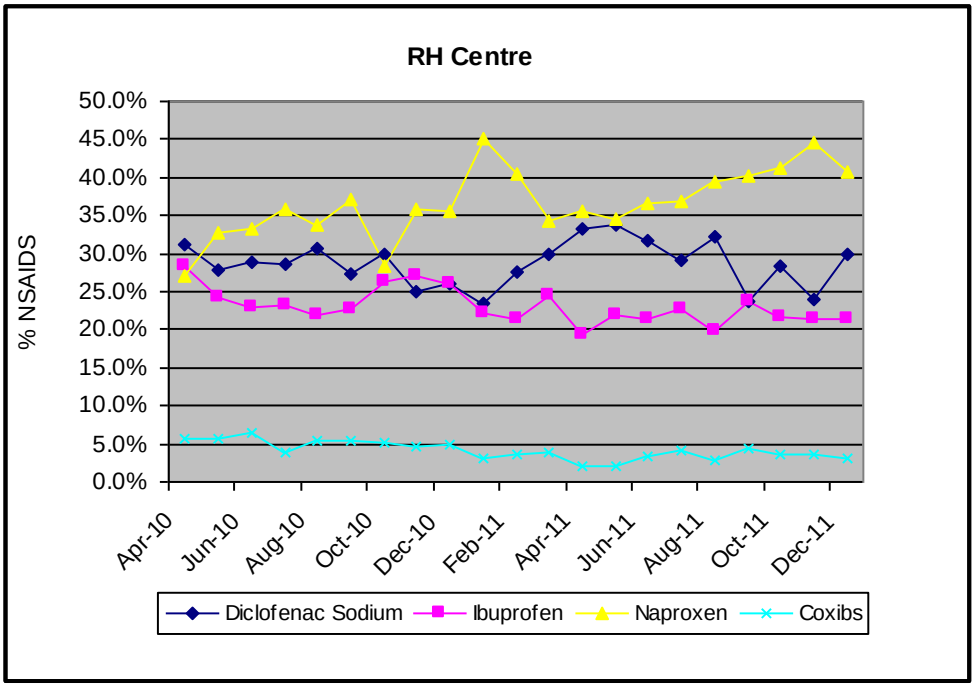


Graph 5.7. NSAIDs Trend Control Practice – OR Surgery

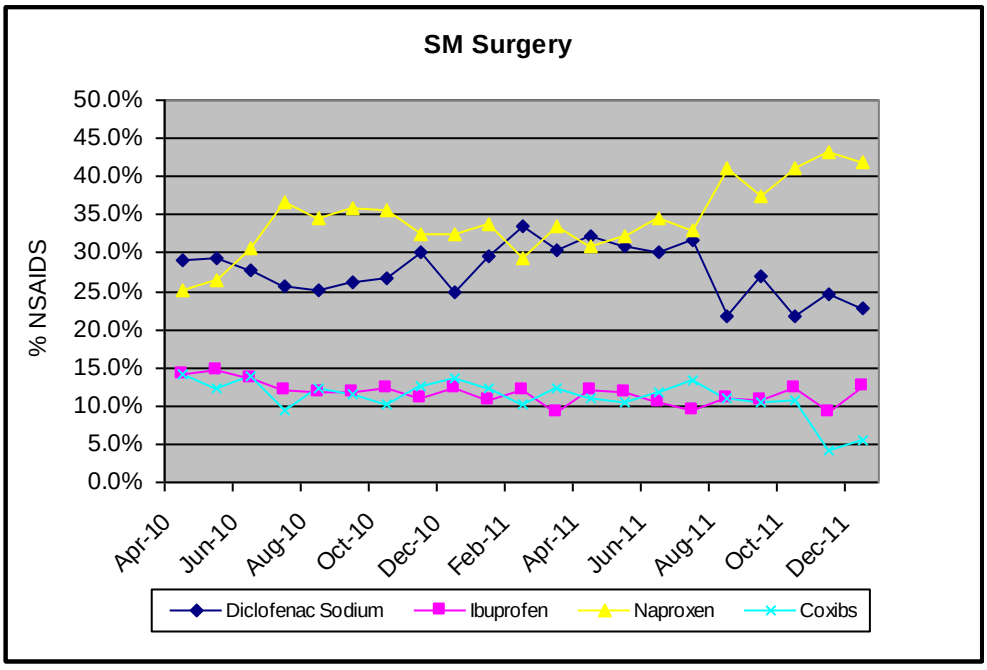


Graph 5.8. NSAIDs Trend Control Practice – PF Surgery

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Control Practices

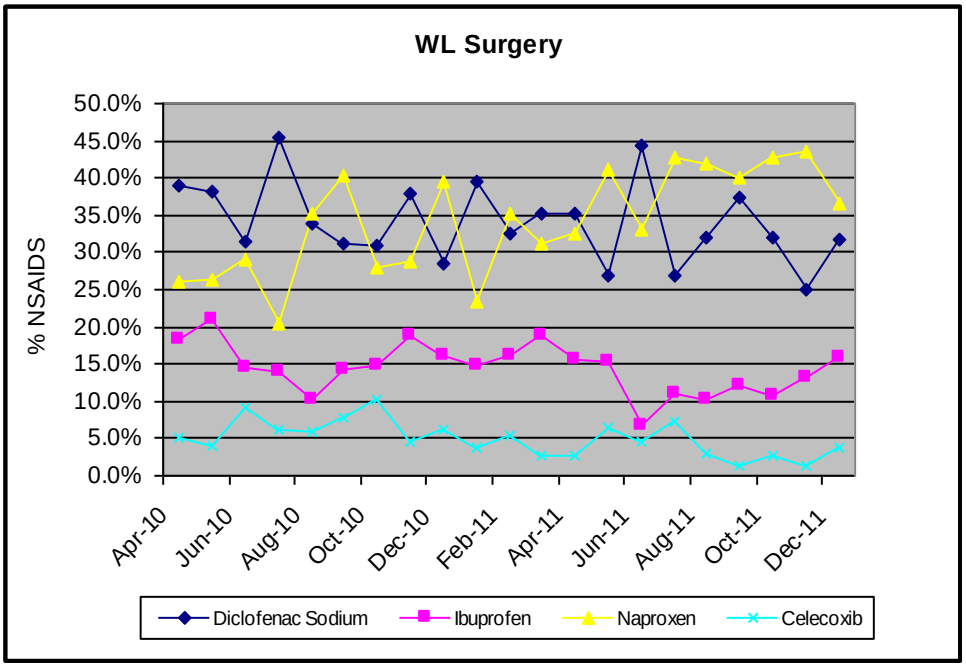


Graph 5.9. NSAIDs Trend Control Practice – RH Centre

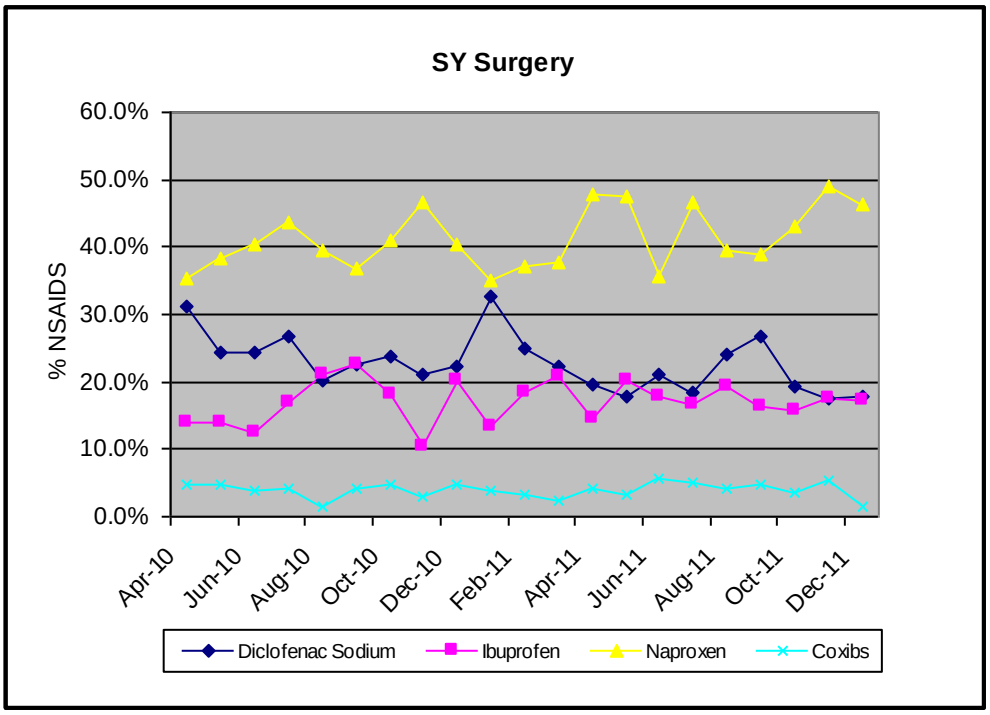


Graph 5.10. NSAIDs Trend Control Practice – SM Surgery

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Control Practices

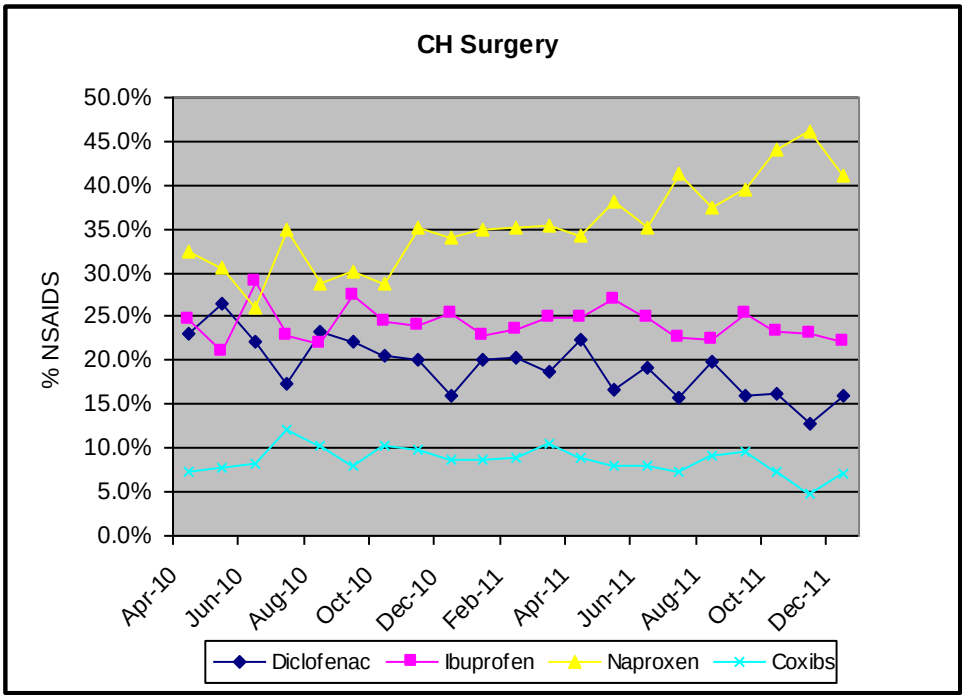


Graph 5.11. NSAIDs Trend Control Practice – WL Surgery

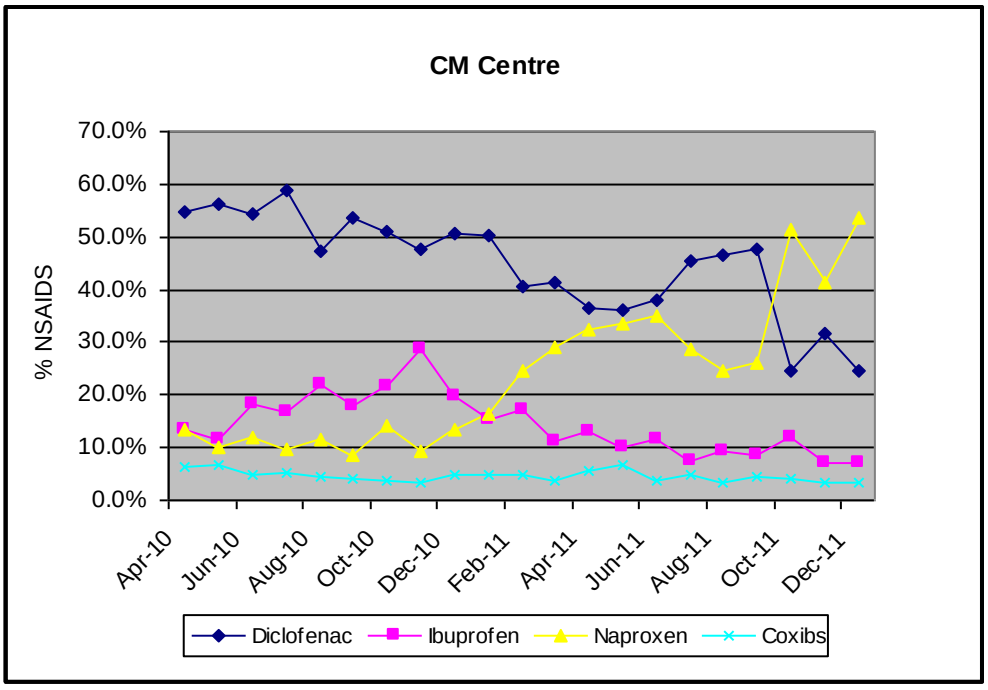


Graph 5.12. NSAIDs Trend Control Practice – SY Surgery

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Intervention Practices

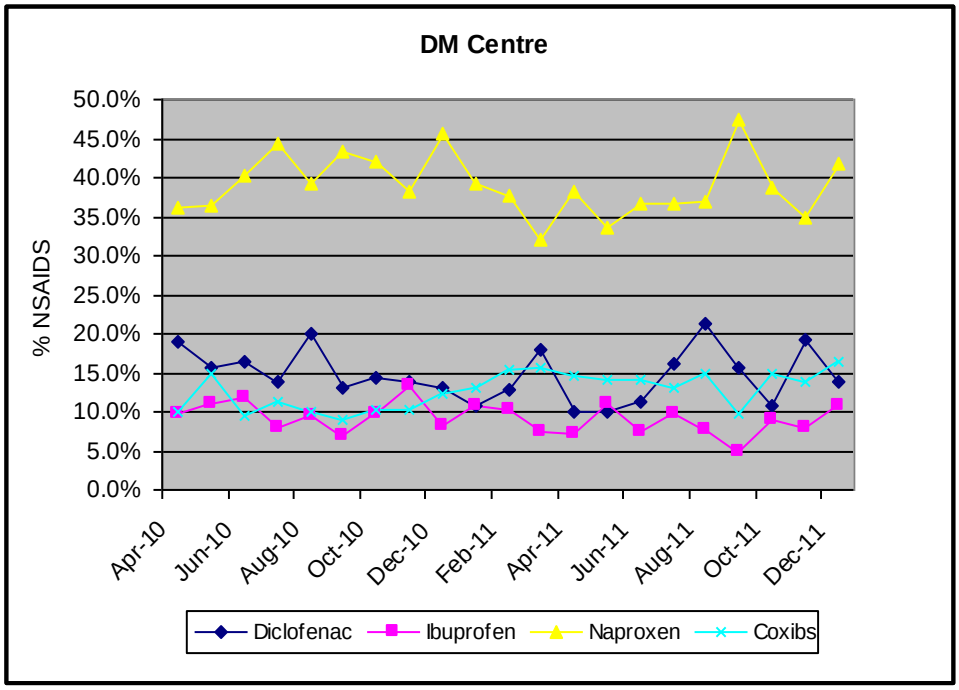


Graph 5.13. NSAIDs Trend Intervention Practice CH Surgery

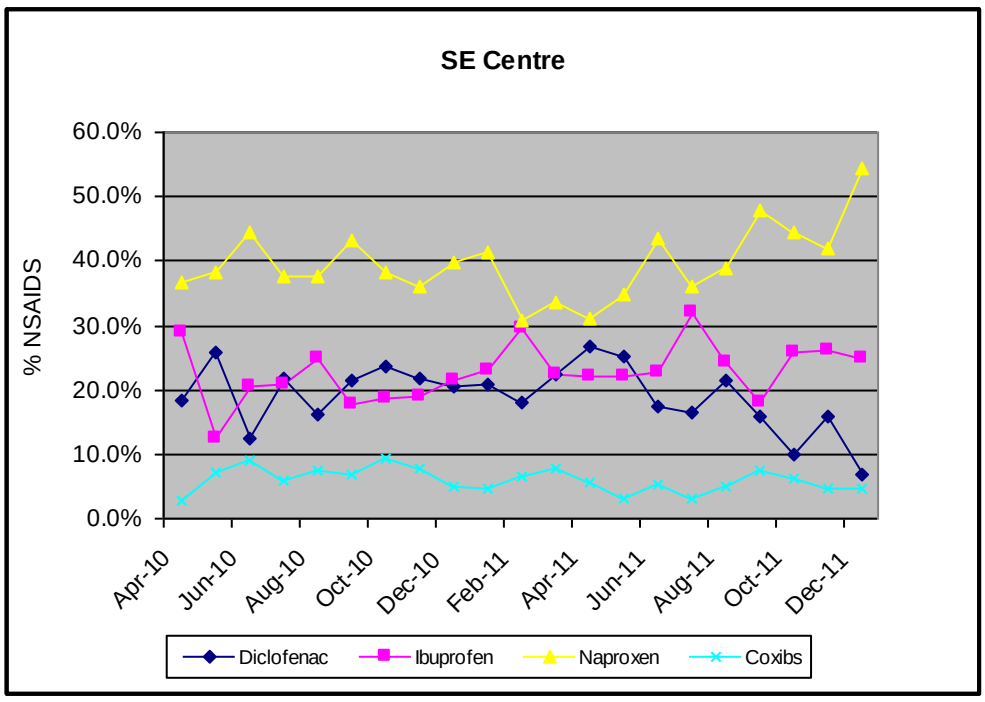


Graph 5.14. NSAIDs Trend Intervention Practice CM Centre

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Intervention Practices

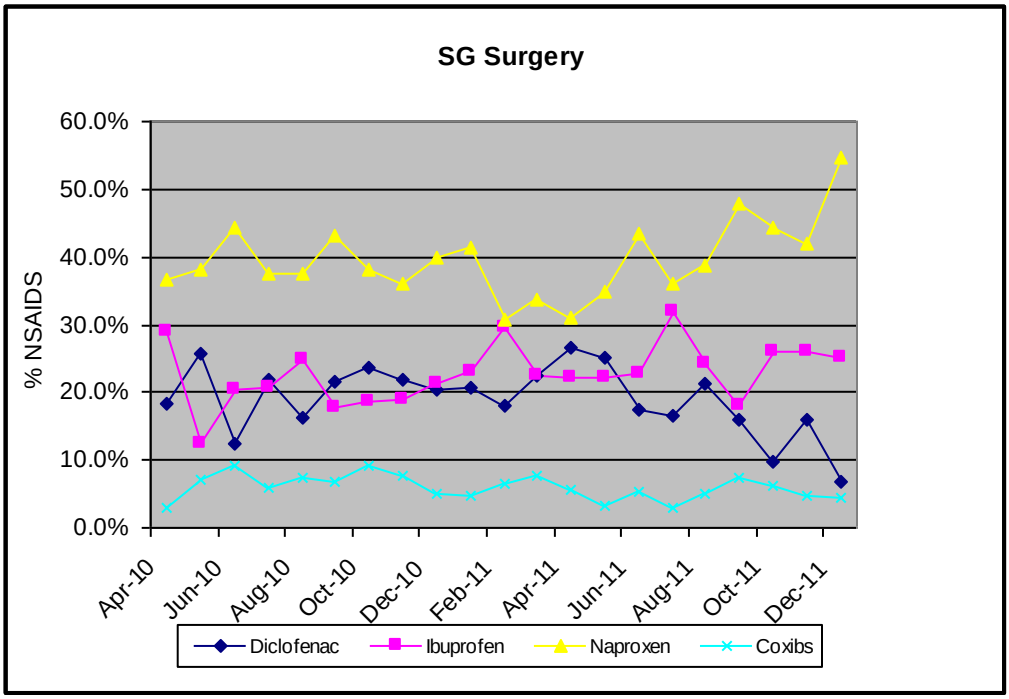


Graph 5.15. NSAIDs Trend Intervention Practice – DM Centre

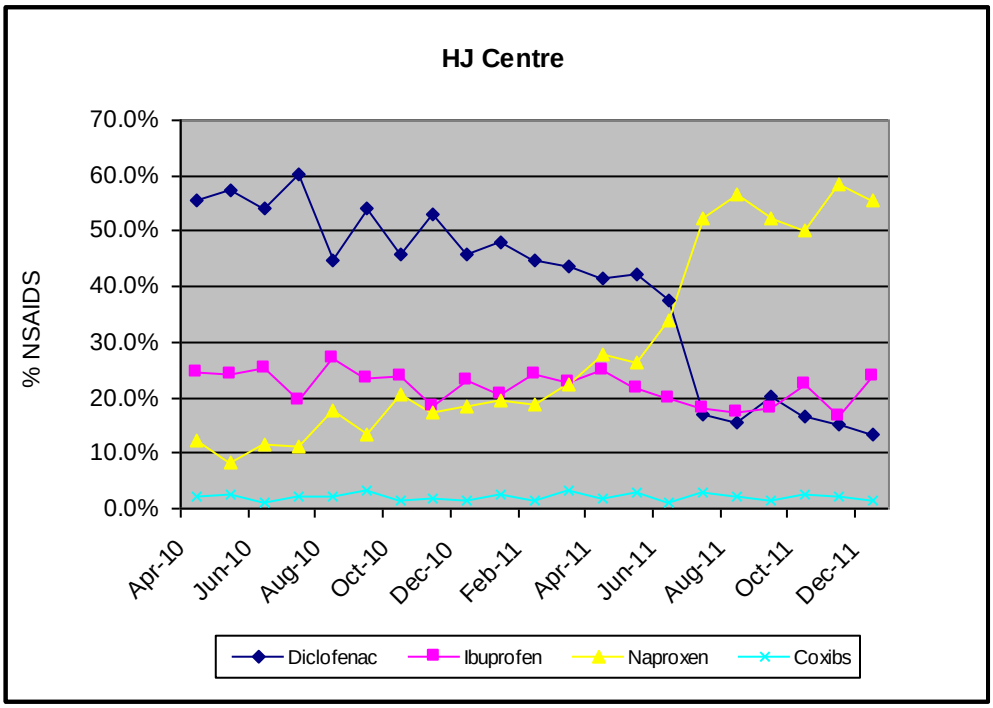


Graph 5.16. NSAIDs Trend Intervention Practice – SE Centre

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Intervention Practices

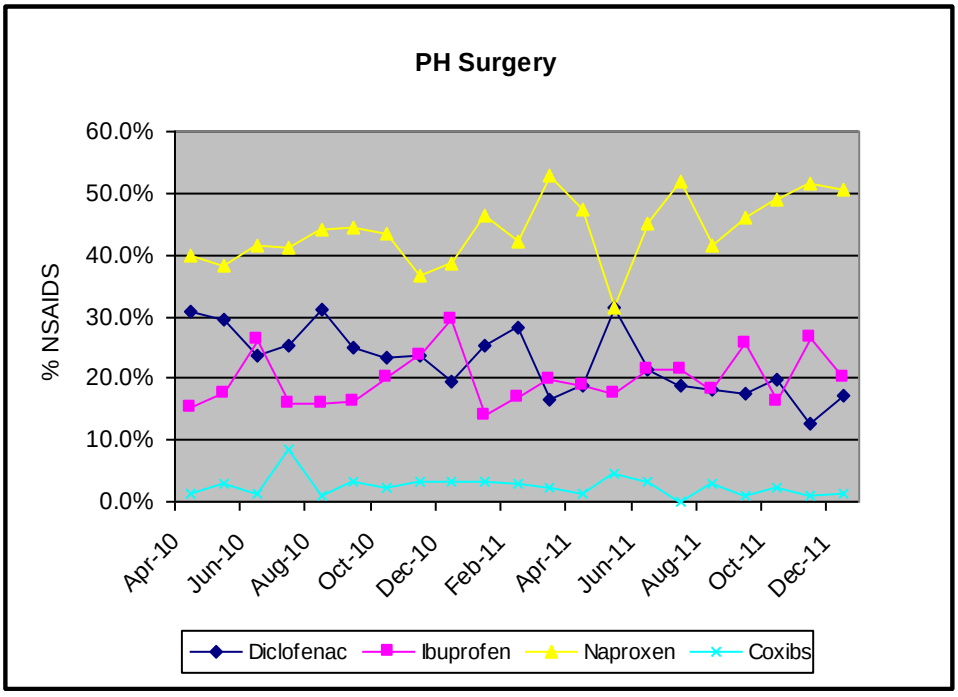


Graph 5.17. NSAIDs Trend Intervention Practice – SG Surgery

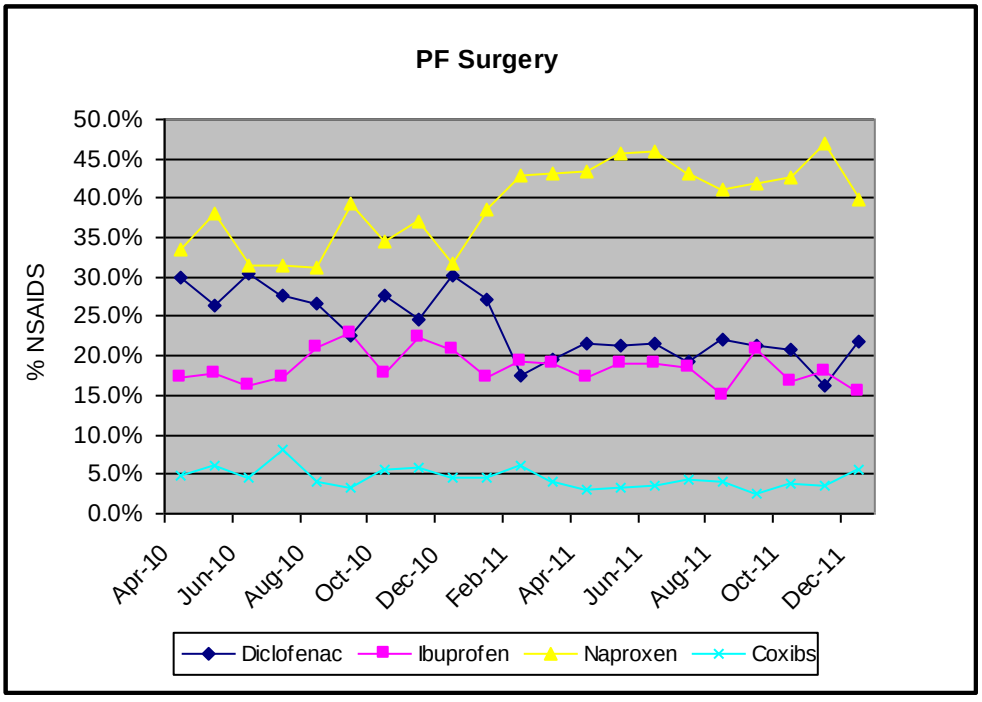


Graph 5.18. NSAIDs Trend Intervention Practice – HJ Centre

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Intervention Practices

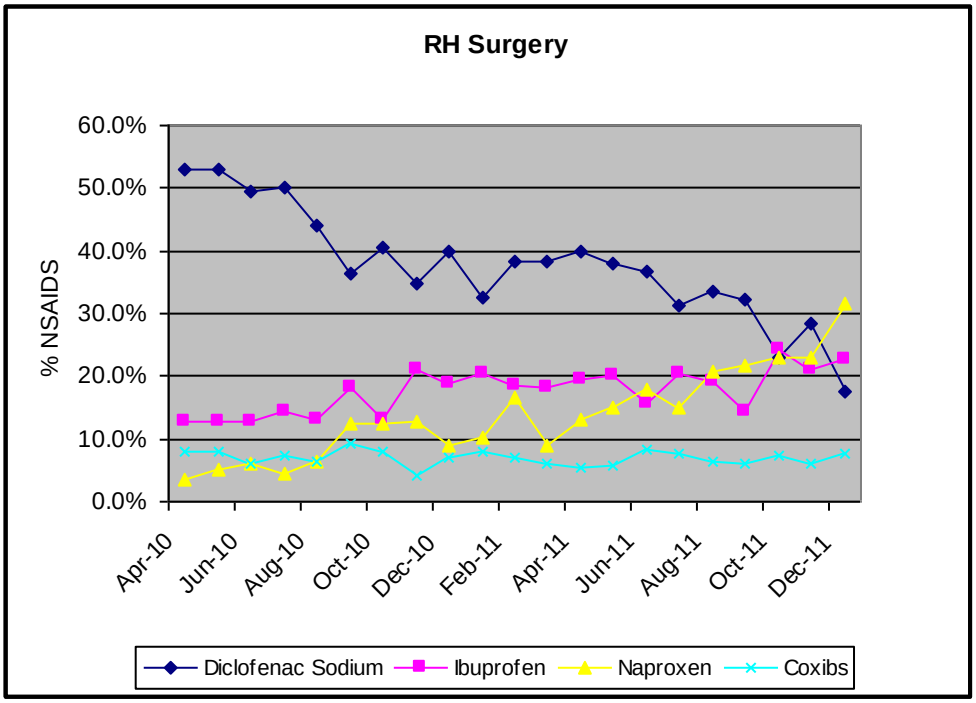


Graph 5.19. NSAIDs Trend Intervention Practice – PH Surgery

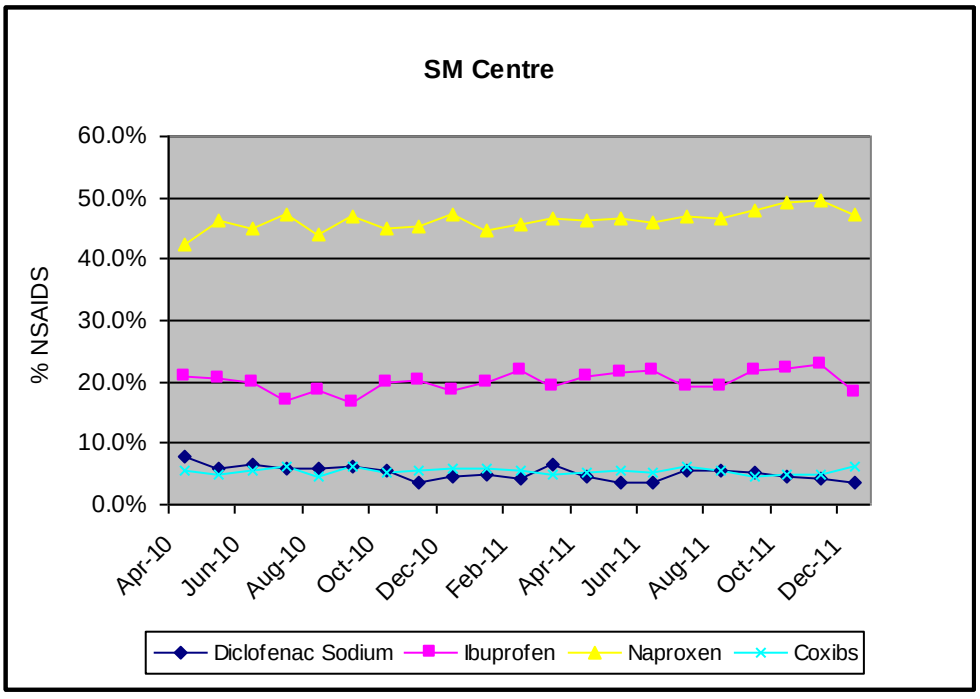


Graph 5.20. NSAIDs Trend Intervention Practice – PF Surgery

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Intervention Practices

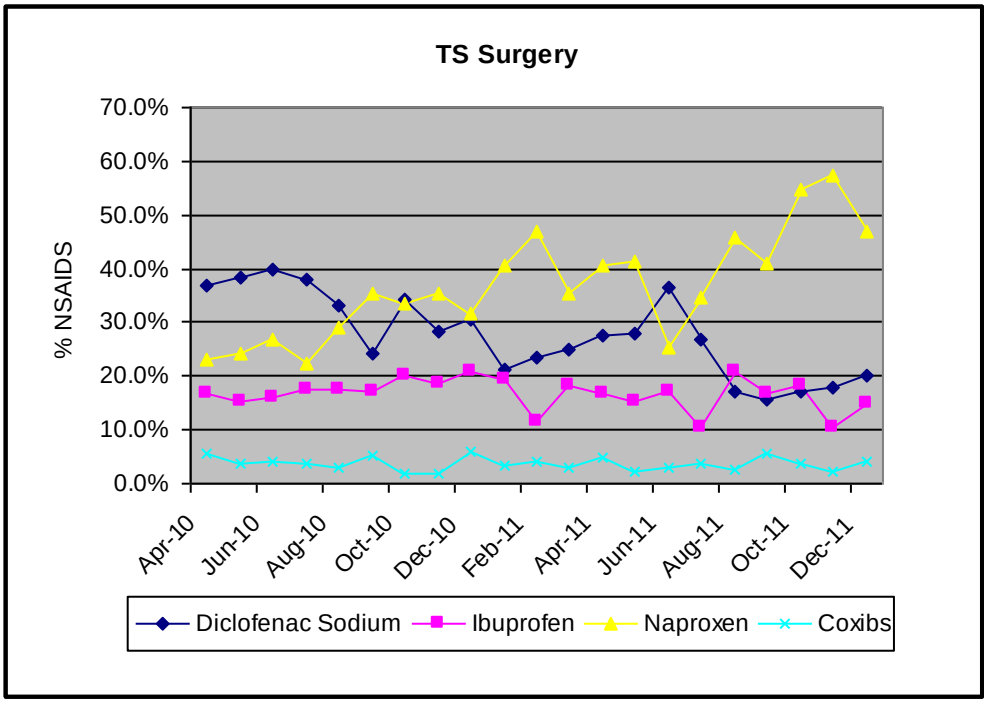


Graph 5.21. NSAIDs Trend Intervention Practice – RH Surgery

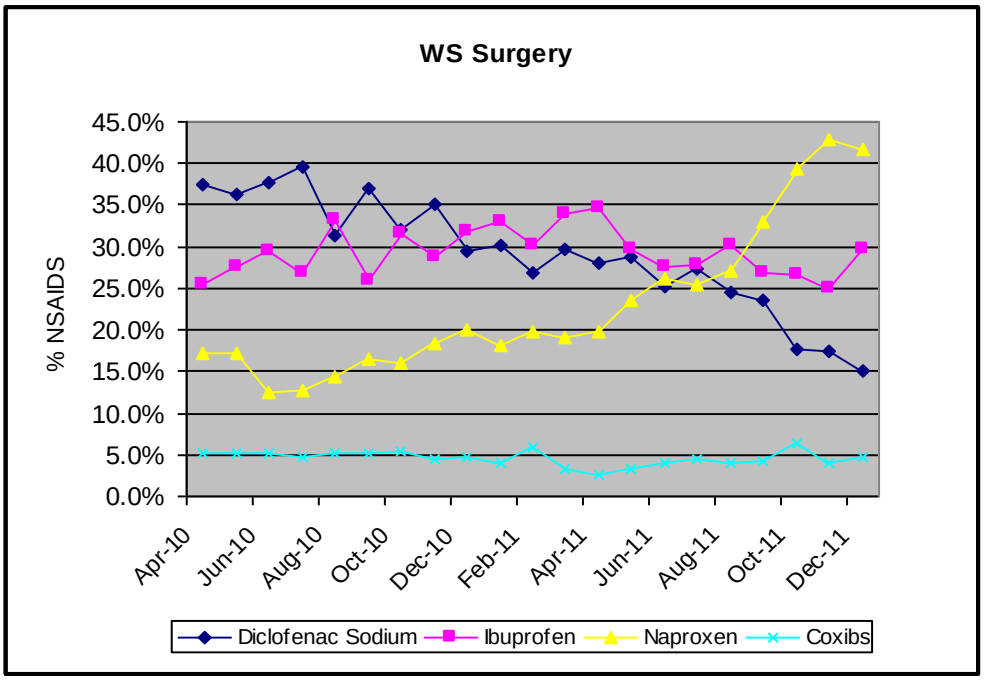


Graph 5.22. NSAIDs Trend Intervention Practice – SM Centre

Non-Steroidal Anti-Inflammatory Drugs Prescribing Trend Data – Individual Intervention Practices



Graph 5.23. NSAIDs Trend Intervention Practice – TS Surgery



Graph 5.24. NSAIDs Trend Intervention Practice – WS Surgery

5.3.1 Non-Steroidal Anti-inflammatory Drugs (Cont)

Individual Practices (Graphs 5.1 to 5.24)

Overall, there were no major changes in individual or general NSAIDs usage over the intervention period in the Control practices. Diclofenac usage ranged from as low as 10% in one practice (MK Centre, Graph 5.5) to as high as 40% in others. Naproxen usage ranged from approximately 25% in some practices to approximately 50% in one practice (MK Centre)

One practice, BW Surgery showed an increase in naproxen from approximately 20% to 40% with a corresponding decrease in diclofenac although this shift occurred towards the end of and following the study intervention period. It most likely reflected specific activity in the practice to address high diclofenac usage. Other practices also showed slight reductions in diclofenac usage with corresponding increases in naproxen following study completion and may have reflected local activities to address NSAID usage.

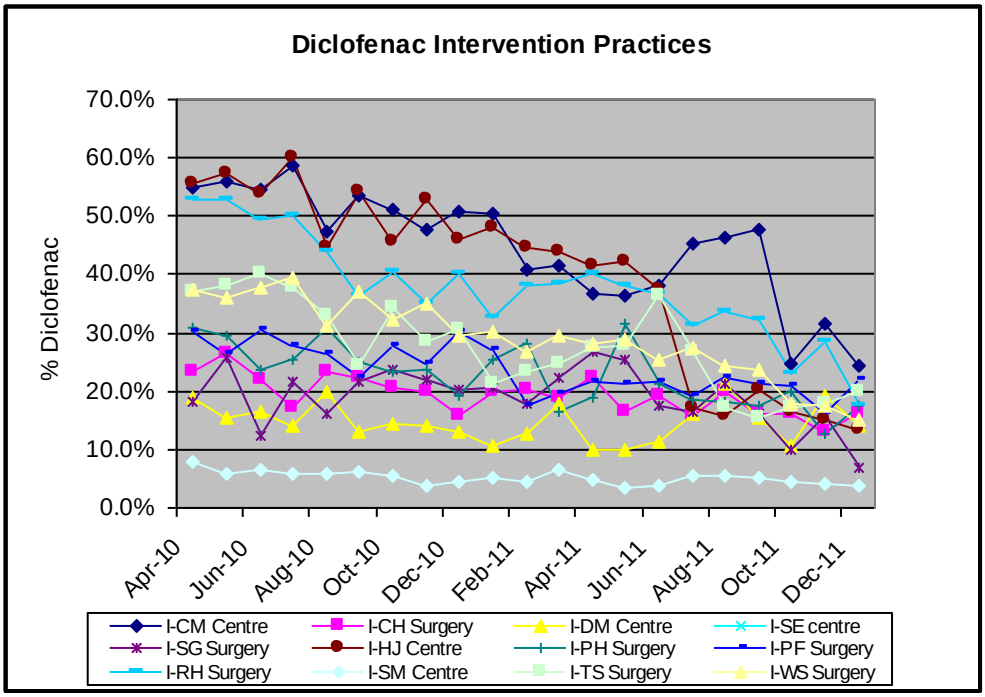
In contrast, a number of intervention practices showed dramatic reductions in diclofenac usage with corresponding increases in naproxen use during the intervention period, which appeared to continue, and were sustained on study completion (CH, SE, SG, HJ, PH, PF, RH, TS, and WS practices). In particular, HJ Centre, RH Surgery, TS Surgery and WS Surgery (Graphs 5.18, 5.21, 5.23, 5.24) demonstrated marked opposing shifts in use of the two drugs.

Pre-intervention Diclofenac usage in intervention practices ranged from 10%-55% and naproxen usage from approximately 10% to 40%. By study completion, naproxen use was 40% or more of total NSAID usage in ten of the twelve intervention practices.

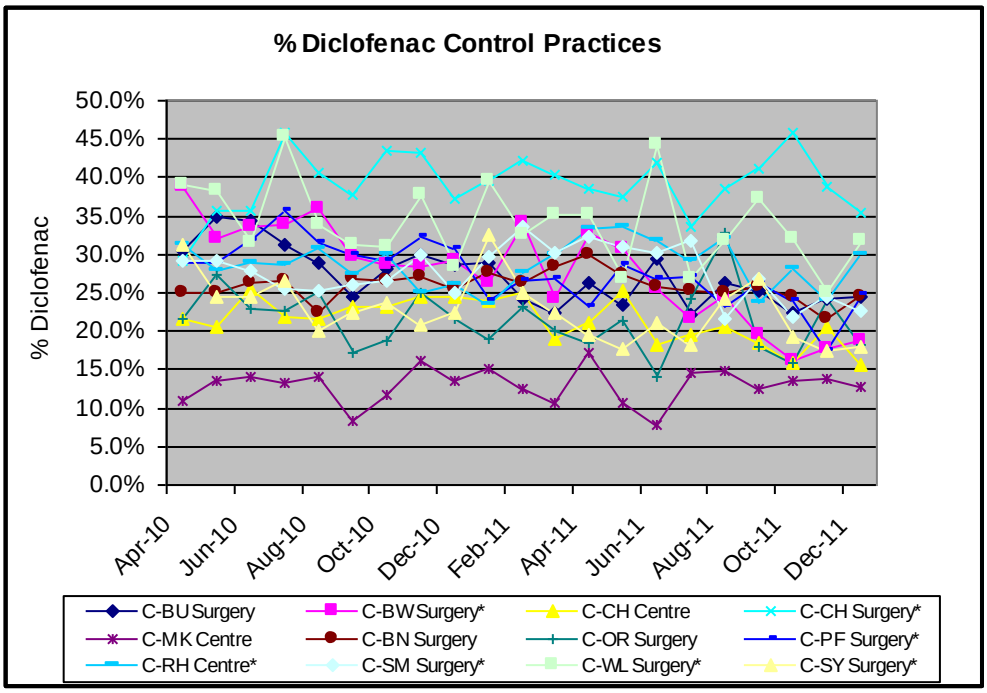
5.3.1.1 Aggregated Prescribing Trend Data

Graph 5.25 shows a clear trend of reduction in prescribing of diclofenac in intervention practices compared with Control (Graph 5.26). There is also an increased trend in prescribing of naproxen in Intervention practices (Graph 5.27) compared with Control (Graph 5.28).

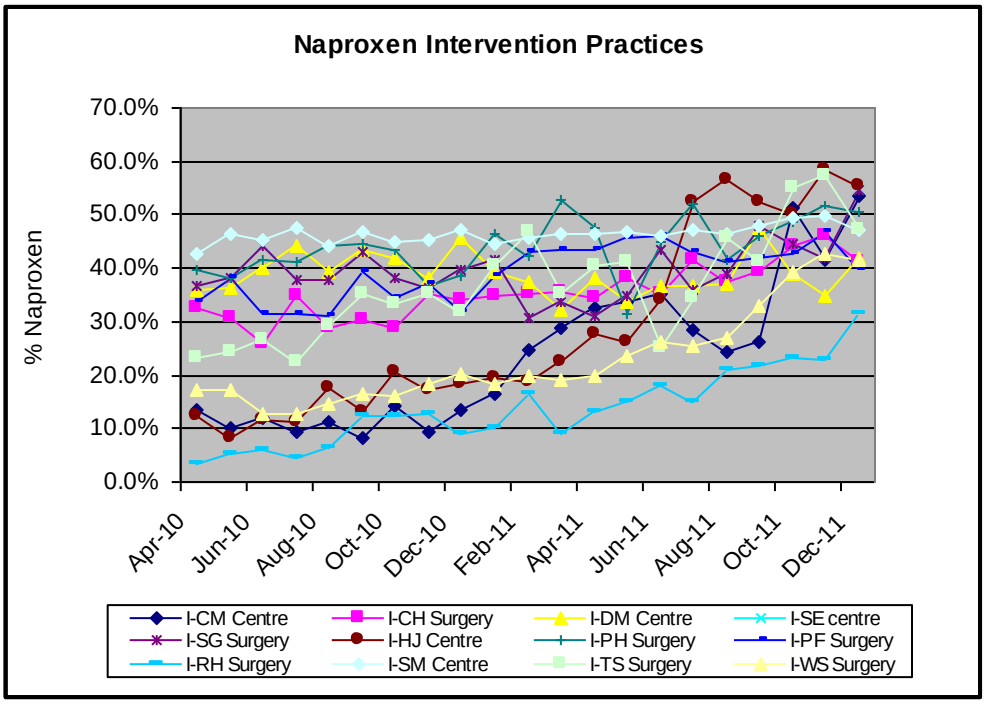
There are no obvious differences in prescribing of Ibuprofen (Graphs 5,29, 5.30) or COX-II Inhibitors (Graphs 5.30, 5.31) in Intervention compared with Control Practices.



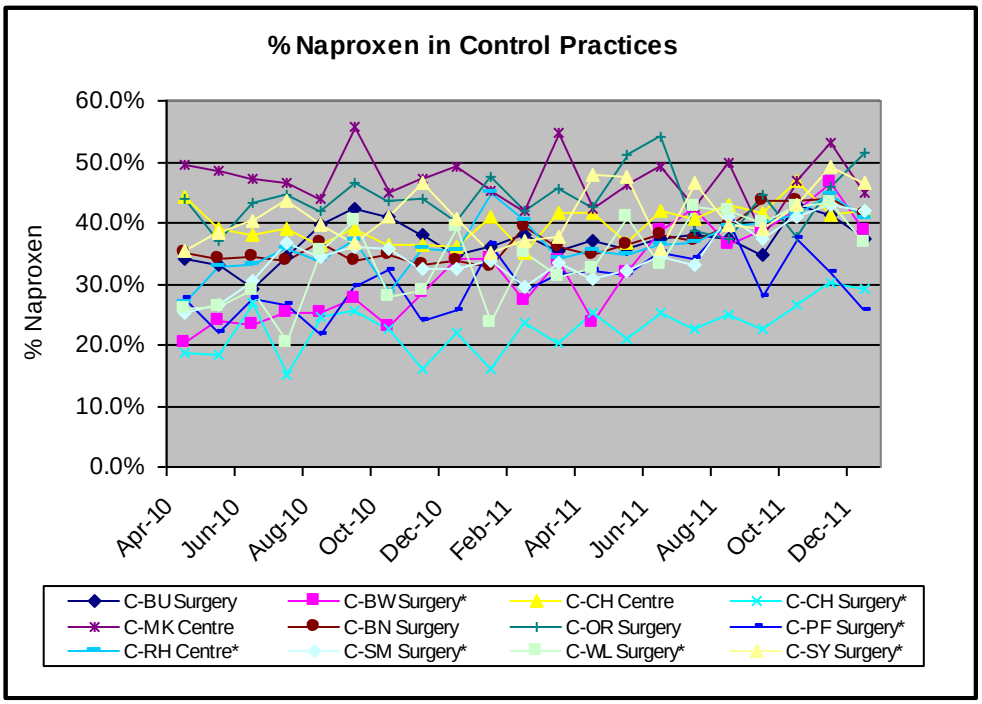
Graph 5.25. Diclofenac Trends – Intervention Practices



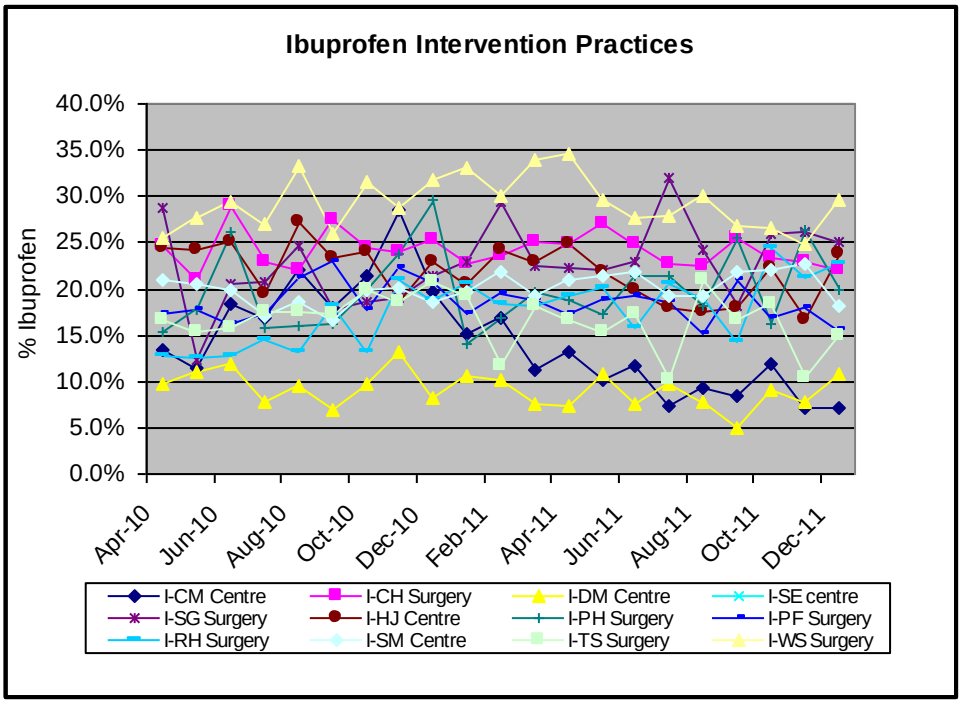
Graph 5.26. Diclofenac Trends – Control Practices



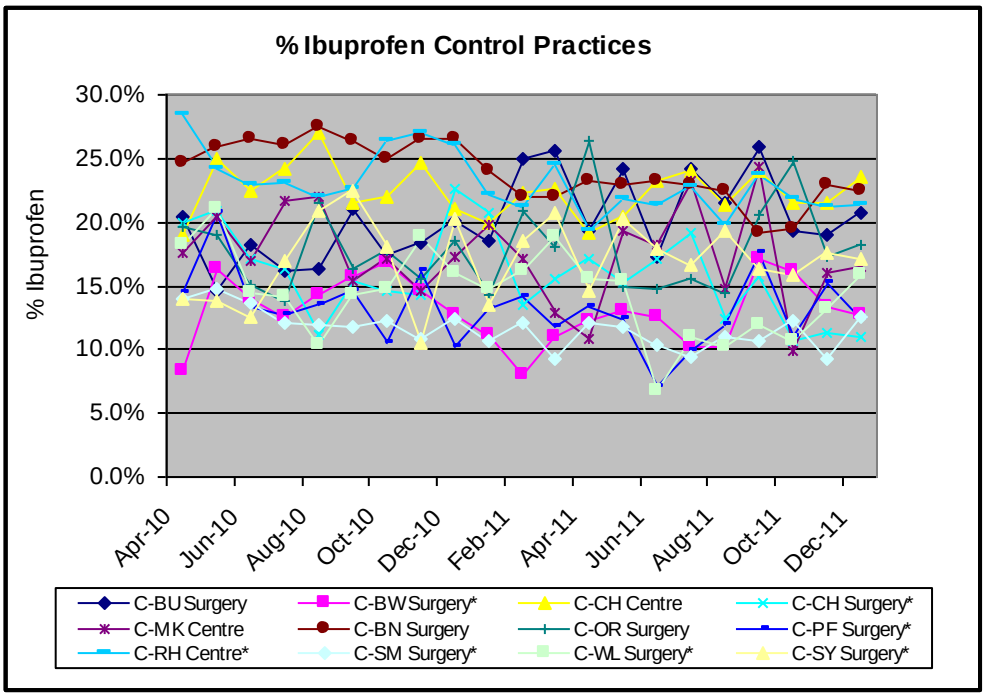
Graph 5.27. Naproxen Trends – Intervention Practices



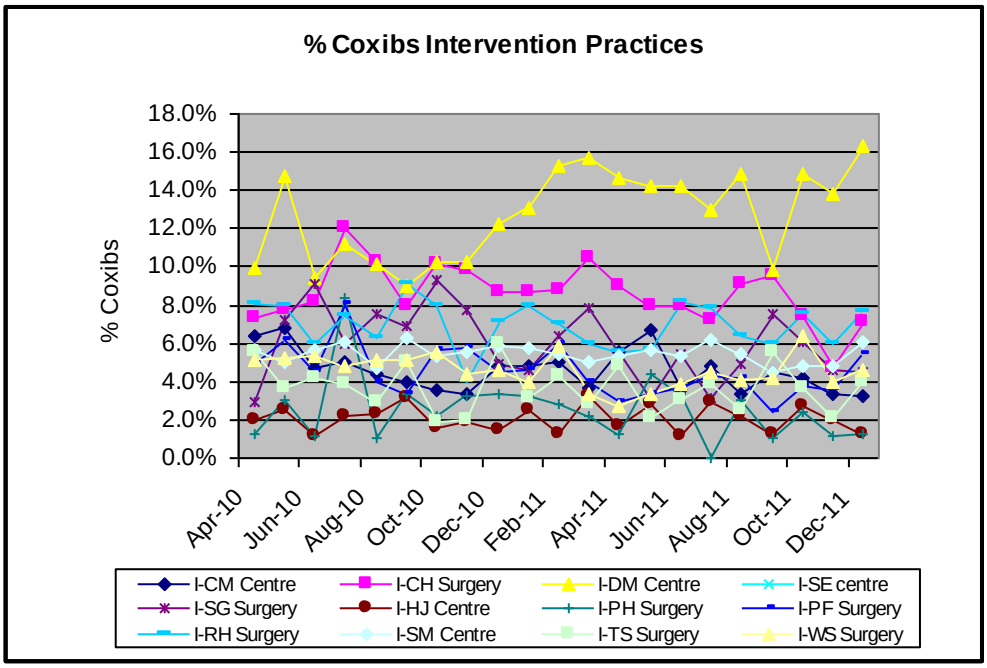
Graph 5.28. Naproxen Trends – Control Practices



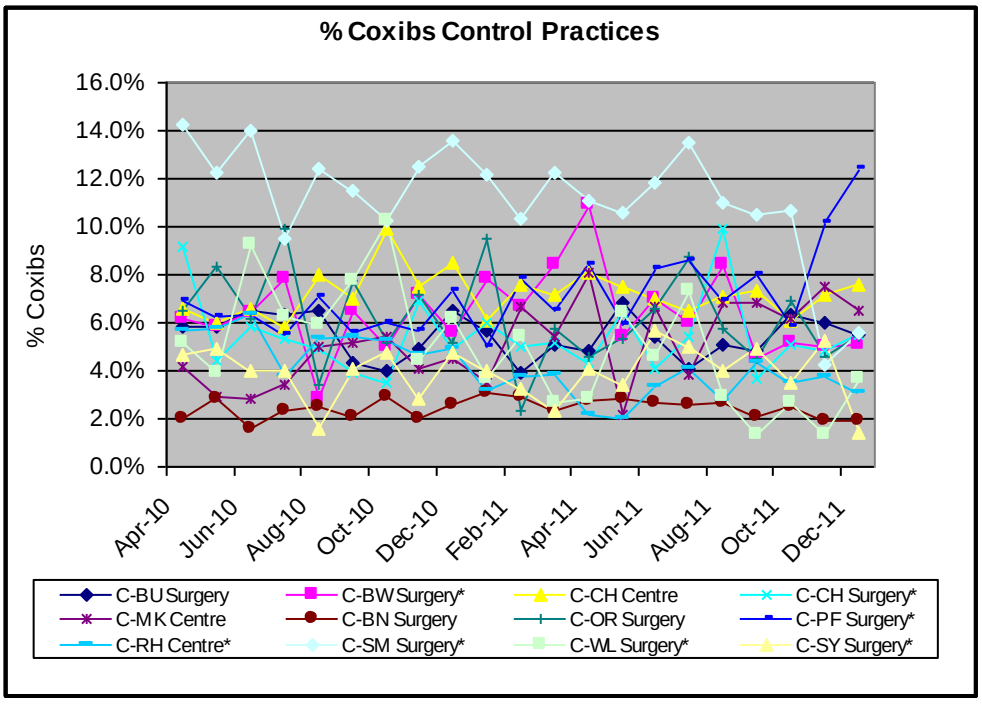
Graph 5.29. Ibuprofen Trends – Intervention Practices



Graph 5.30. Ibuprofen Trends – Control Practices



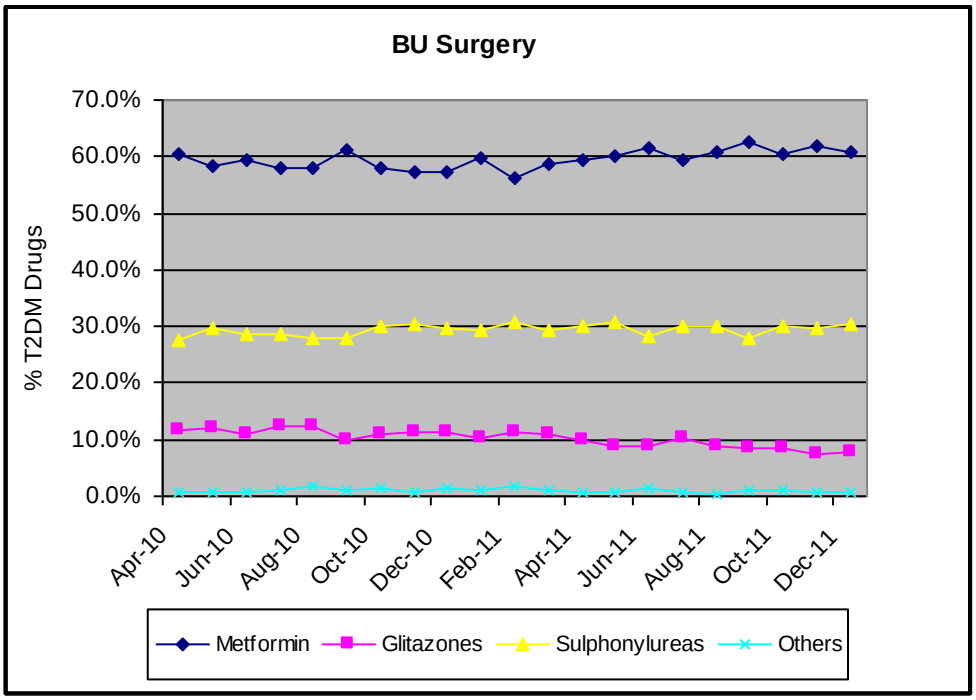
Graph 5.31. COX-II Inhibitor Trends – Intervention Practices



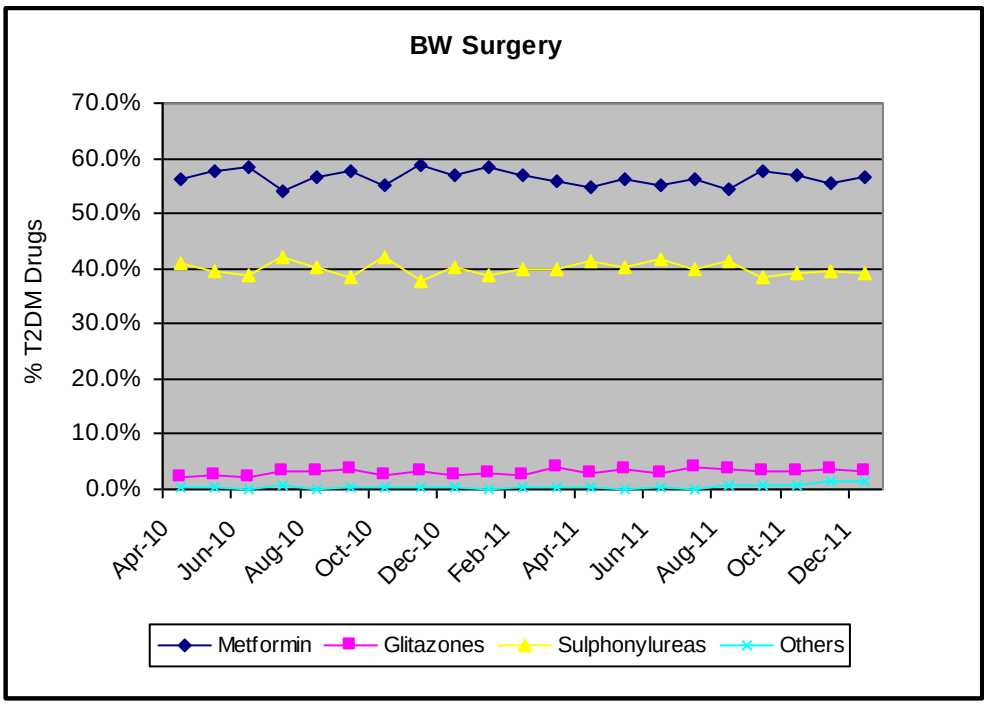
Graph 5.32. COX-II Inhibitor Trends – Control Practices

5.3.2 Drugs Used in Type 2 Diabetes

Drugs used in T2DM Prescribing Trend Data – Individual Control Practices

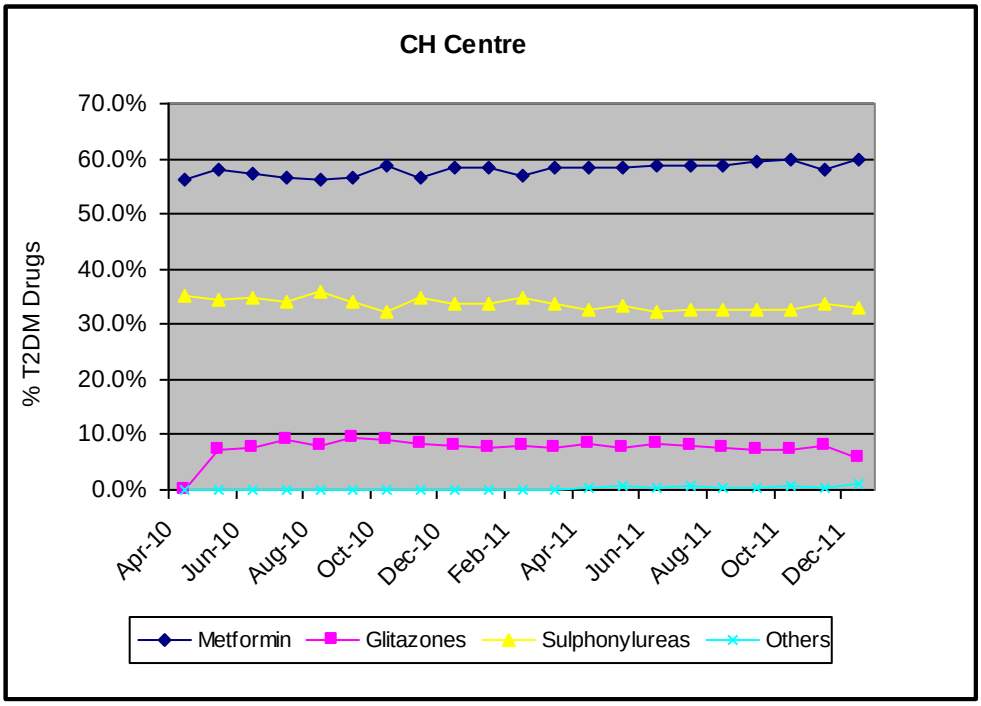


Graph 5.33. T2DM Drugs Trend Control Practices – BU Surgery

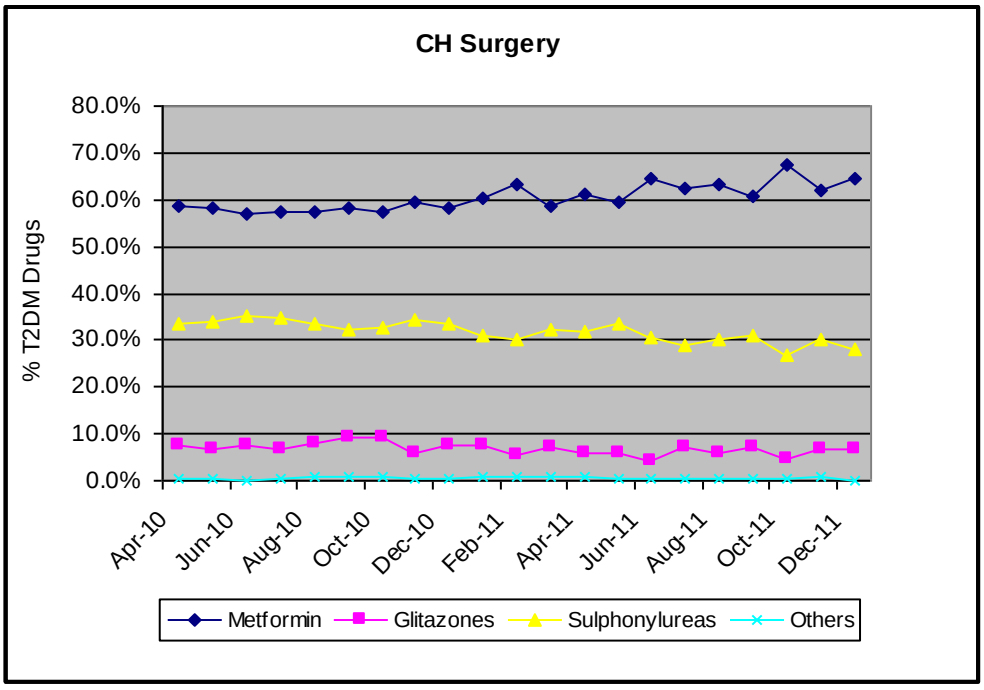


Graph 5.34. T2DM Drugs Trend Control Practices – BW Surgery

Drugs used in T2DM Prescribing Trend Data – Individual Control Practices

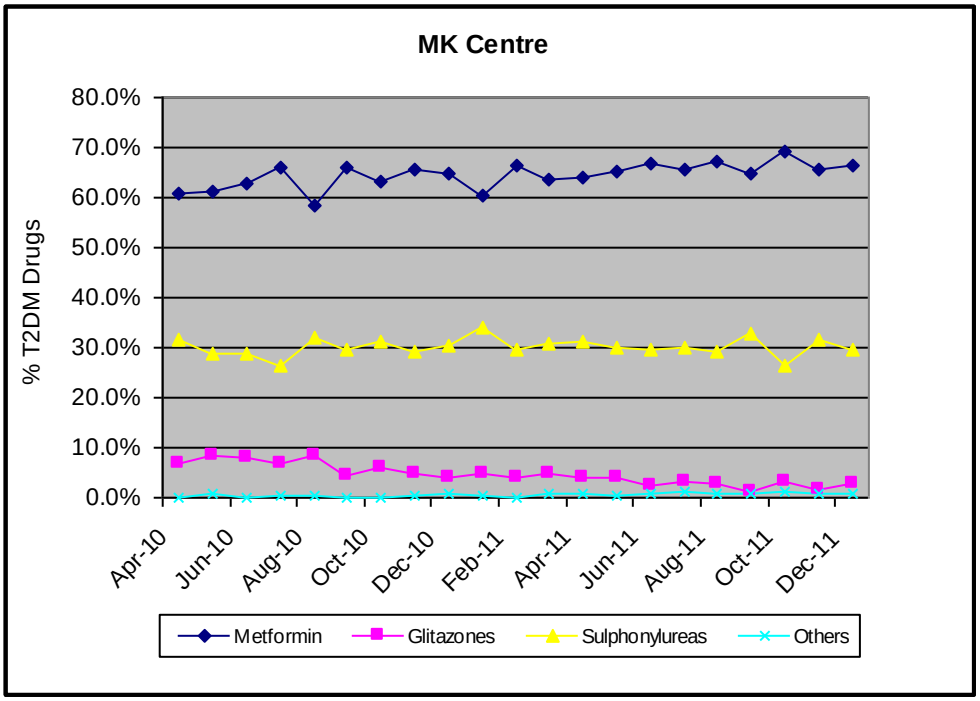


Graph 5.35. T2DM Drugs Trend Control Practices – CH Centre

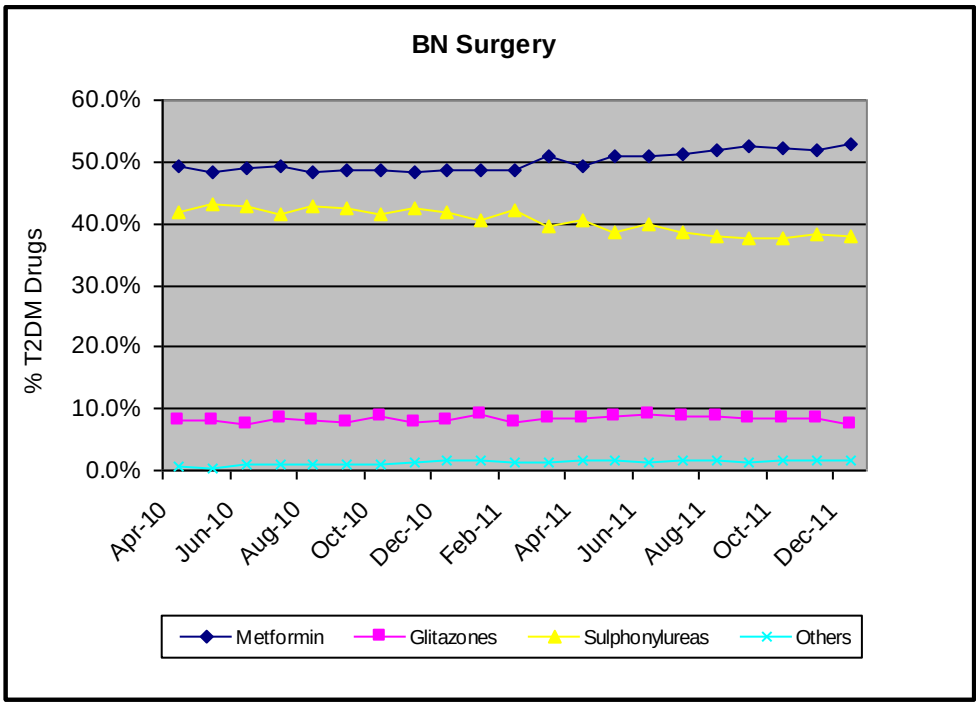


Graph 5.36. T2DM Drugs Trend Control Practices – CH Surgery

Drugs used in T2DM Prescribing Trend Data – Individual Control Practices

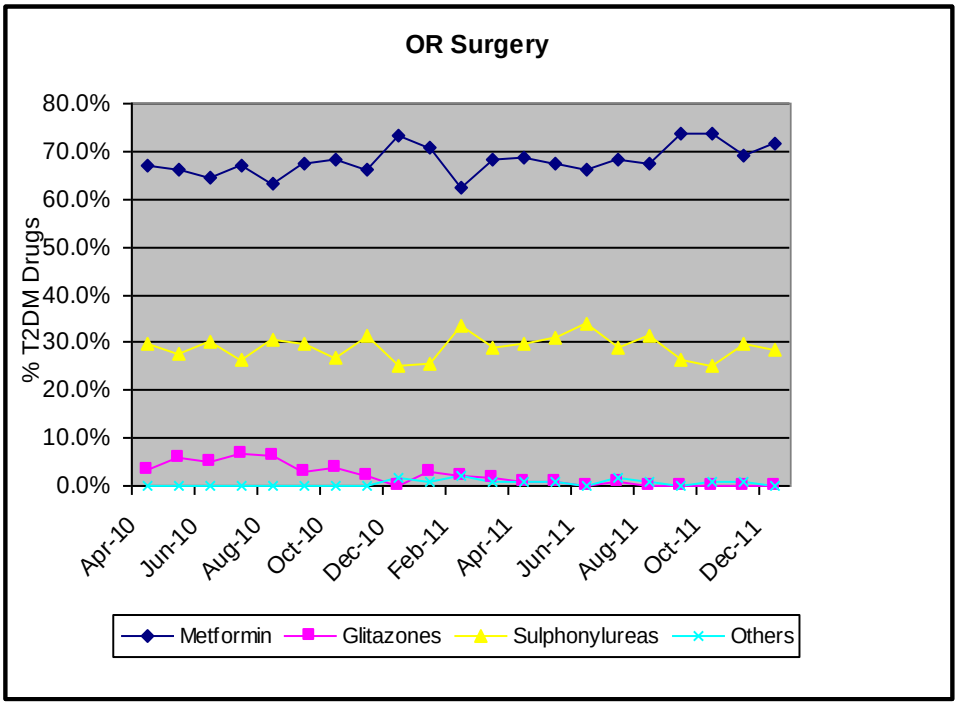


Graph 5.37. T2DM Drugs Trend Control Practices – MK Centre

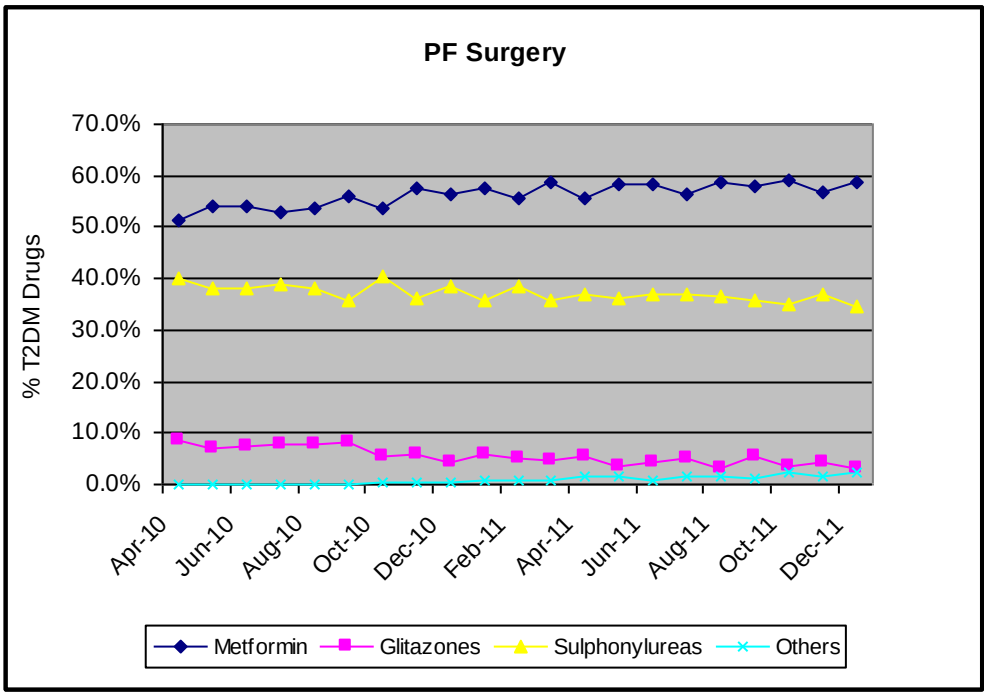


Graph 5.38. T2DM Drugs Trend Control Practices – BN Surgery

Drugs used in T2DM Prescribing Trend Data – Individual Control Practices

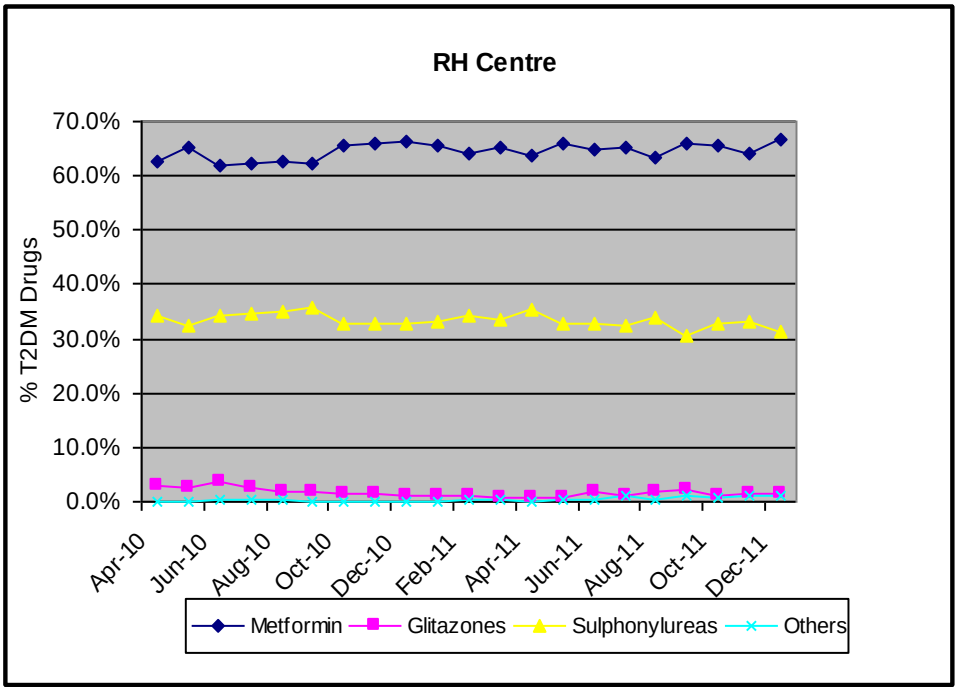


Graph 5.39. T2DM Drugs Trend Control Practices – OR Surgery

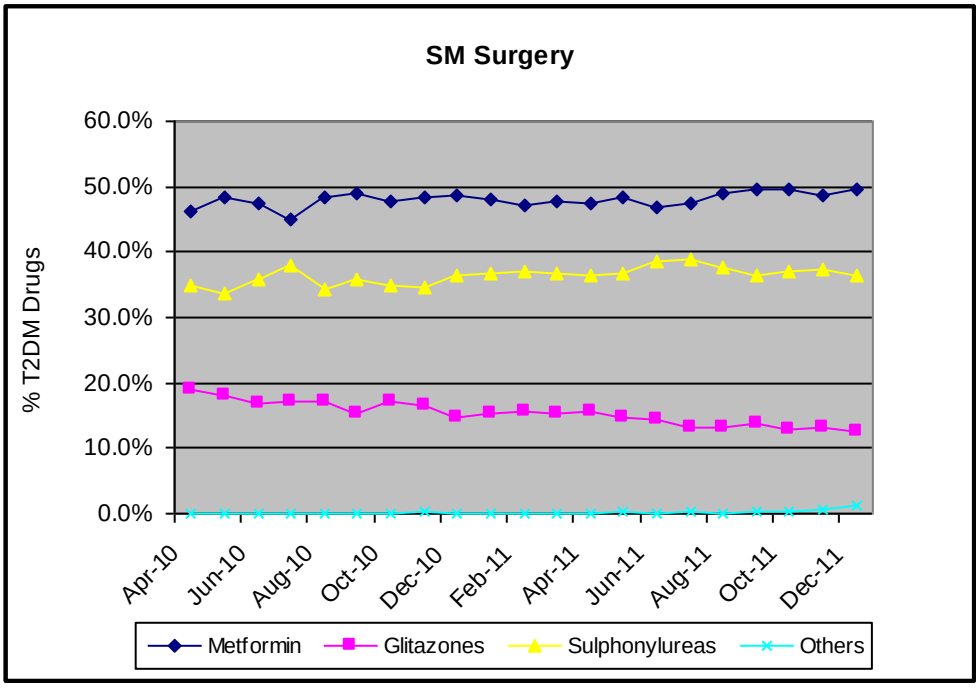


Graph 5.40 T2DM Drugs Trend Control Practices – PF Surgery

Drugs used in T2DM Prescribing Trend Data – Individual Control Practices

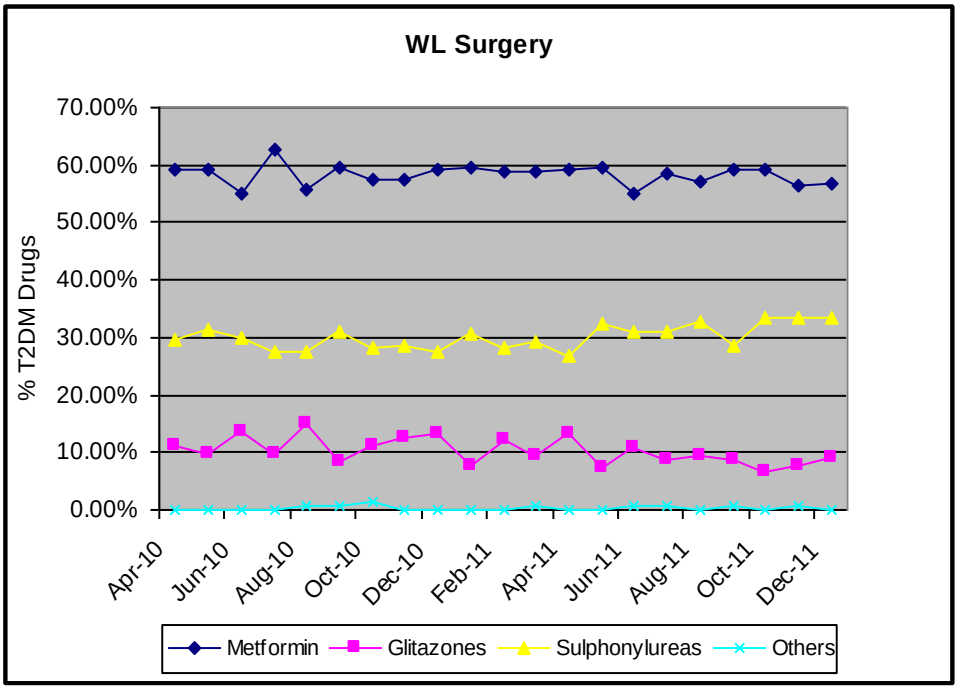


Graph 5.41. T2DM Drugs Trend Control Practices – RH Centre

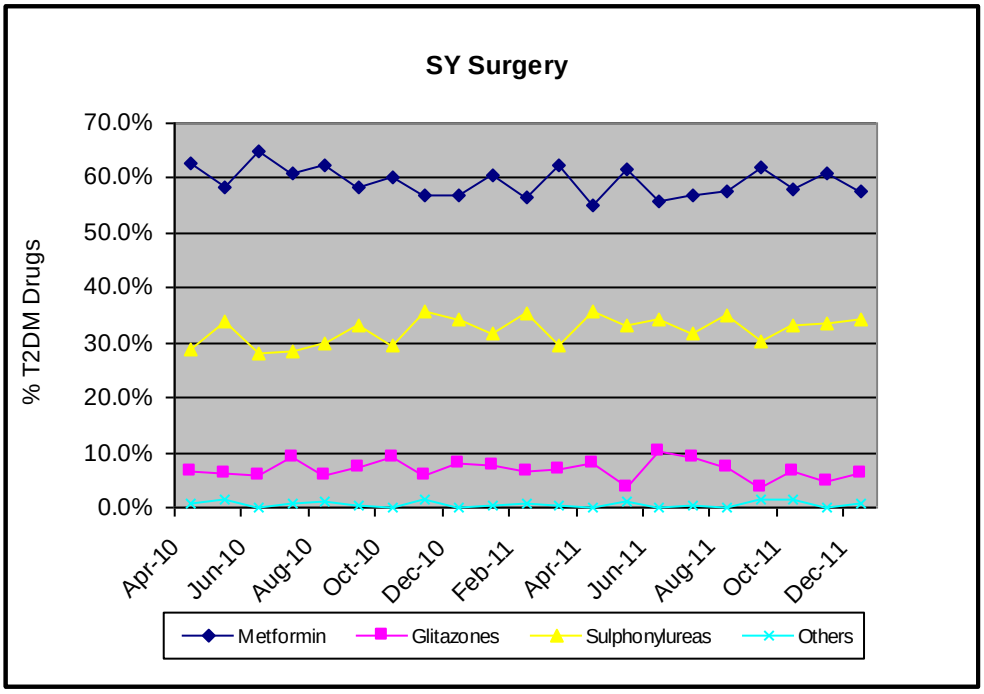


Graph 5.42. T2DM Drugs Trend Control Practices – SM Surgery

Drugs used in T2DM Prescribing Trend Data – Individual Control Practices

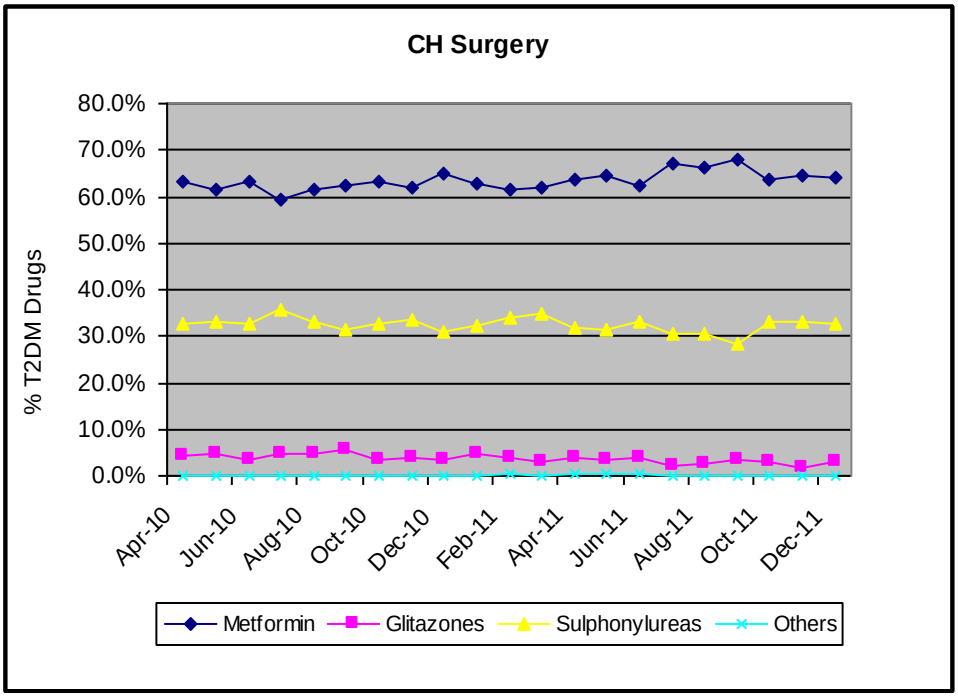


Graph 5.43. T2DM Drugs Trend Control Practices – WL Surgery

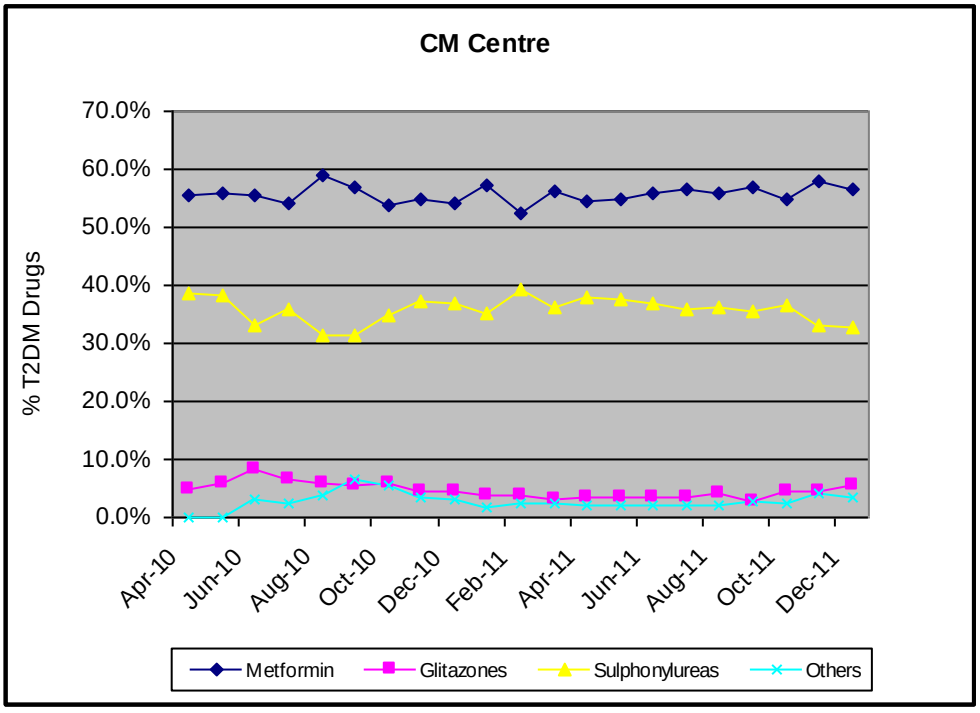


Graph 5.44. T2DM Drugs Trend Control Practices – SY Surgery

Drugs used in T2DM Prescribing Trend Data – Individual Intervention Practices

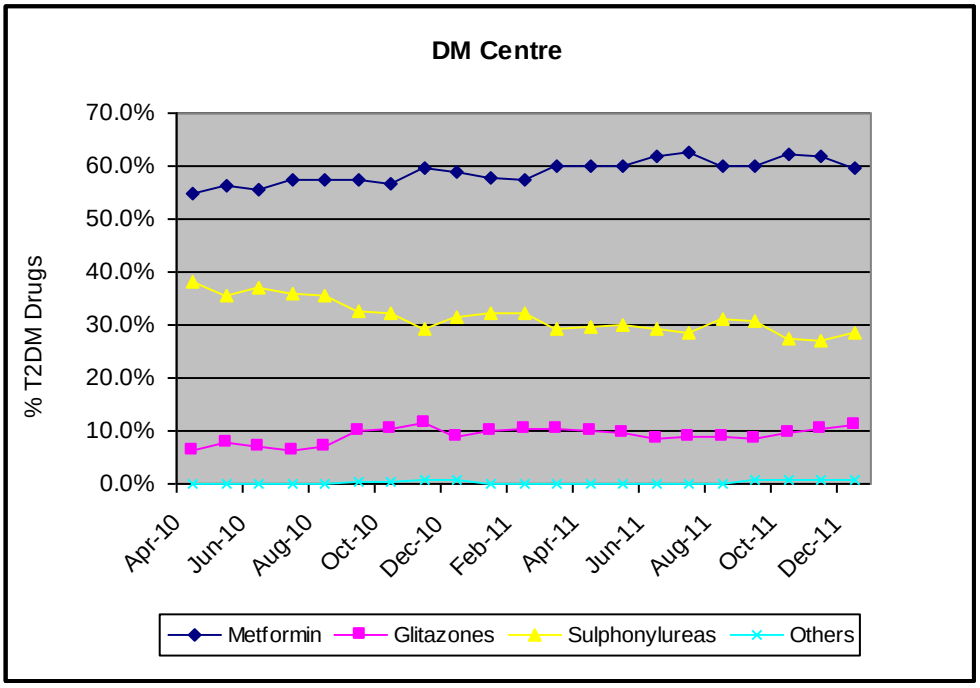


Graph 5.45. T2DM Drugs Trend Intervention Practices – CH Surgery

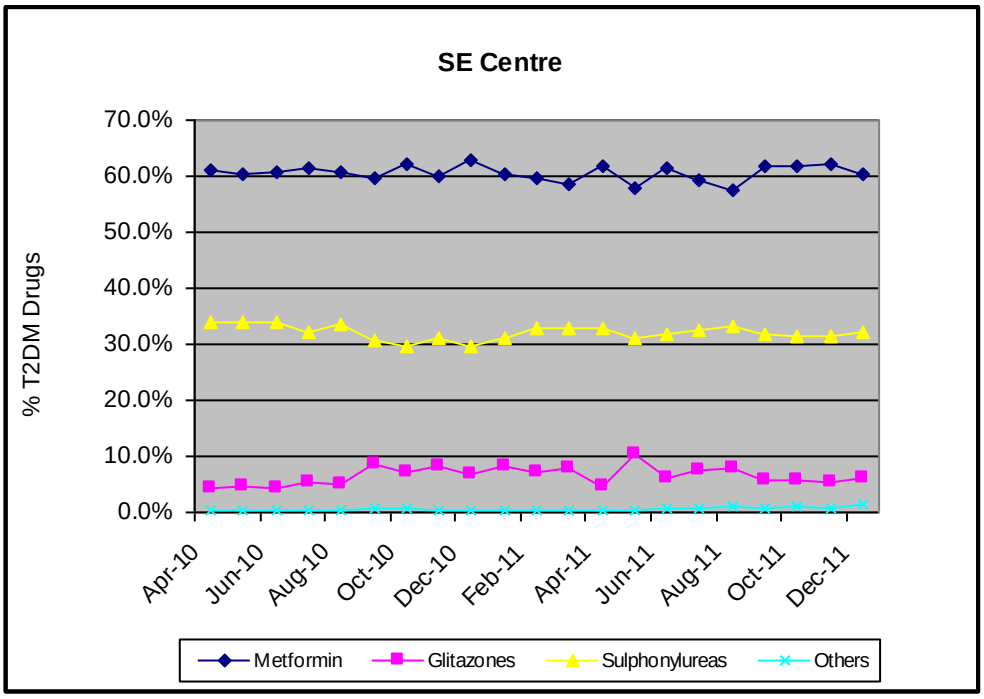


Graph 5.46 T2DM Drugs Trend Intervention Practices – CM Centre

Drugs used in T2DM Prescribing Trend Data – Individual Intervention Practices

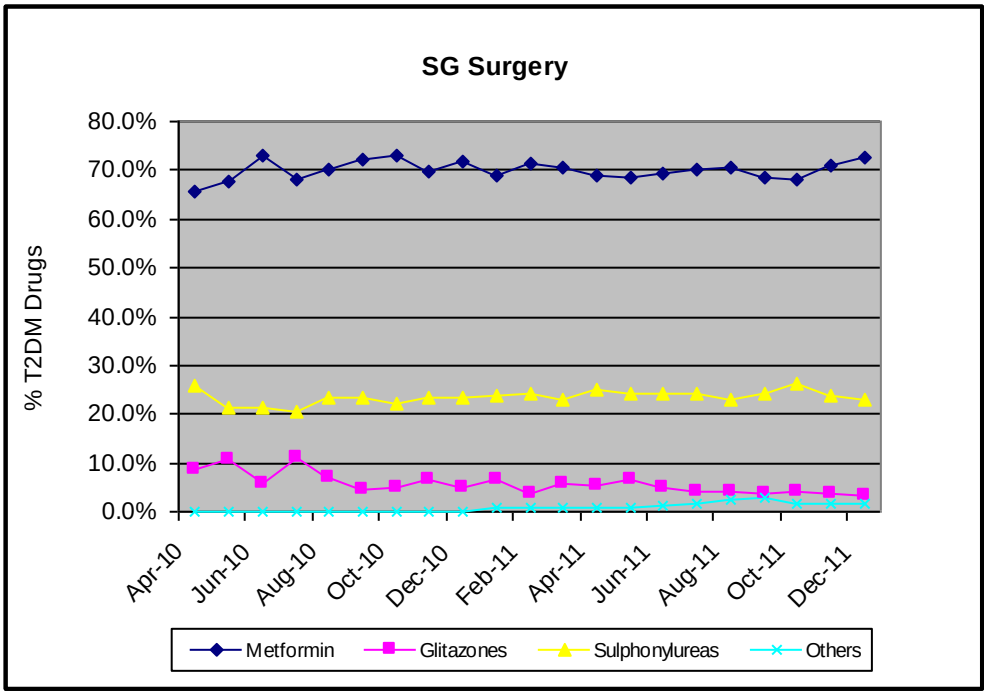


Graph 5.47. T2DM Drugs Trend Intervention Practices – DM Centre

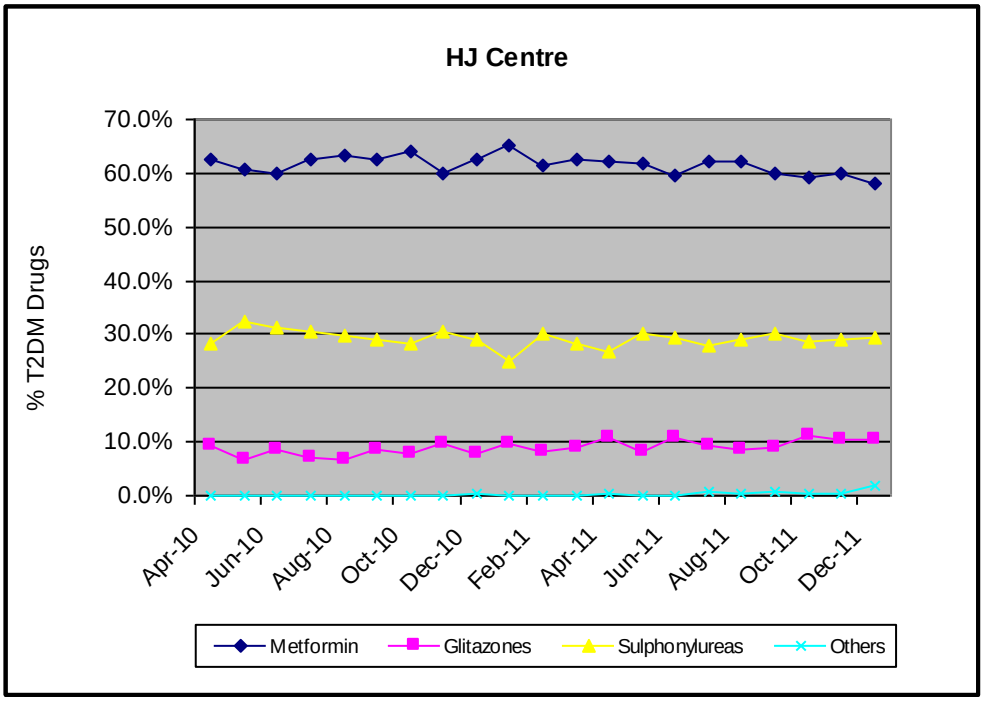


Graph 5.48. T2DM Drugs Trend Intervention Practices – SE Centre

Drugs used in T2DM Prescribing Trend Data – Individual Intervention Practices

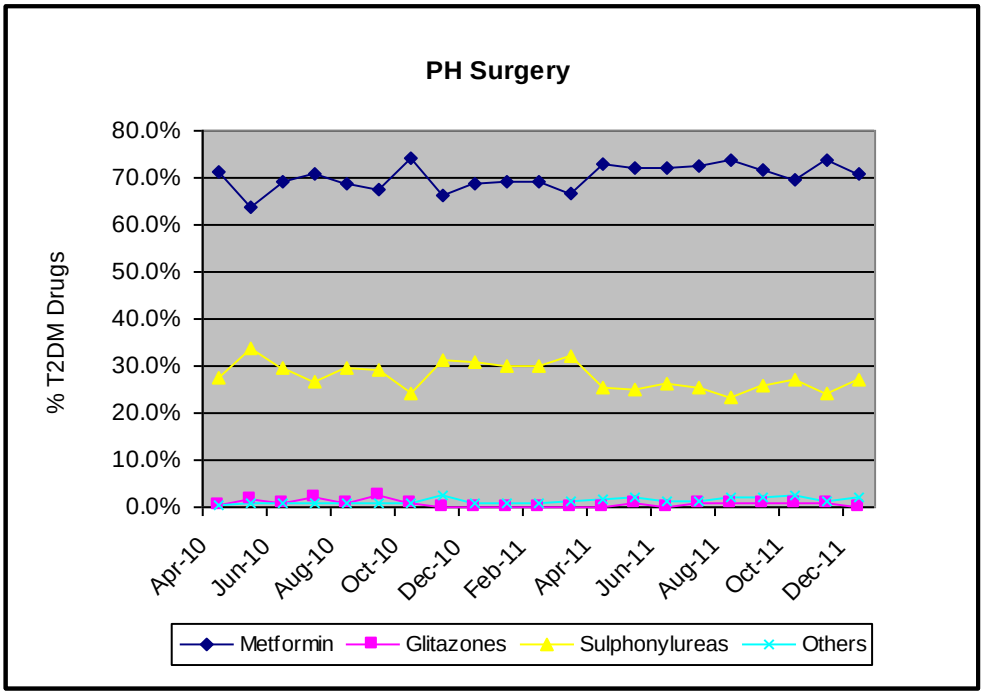


Graph 5.49. T2DM Drugs Trend Intervention Practices – SG Surgery

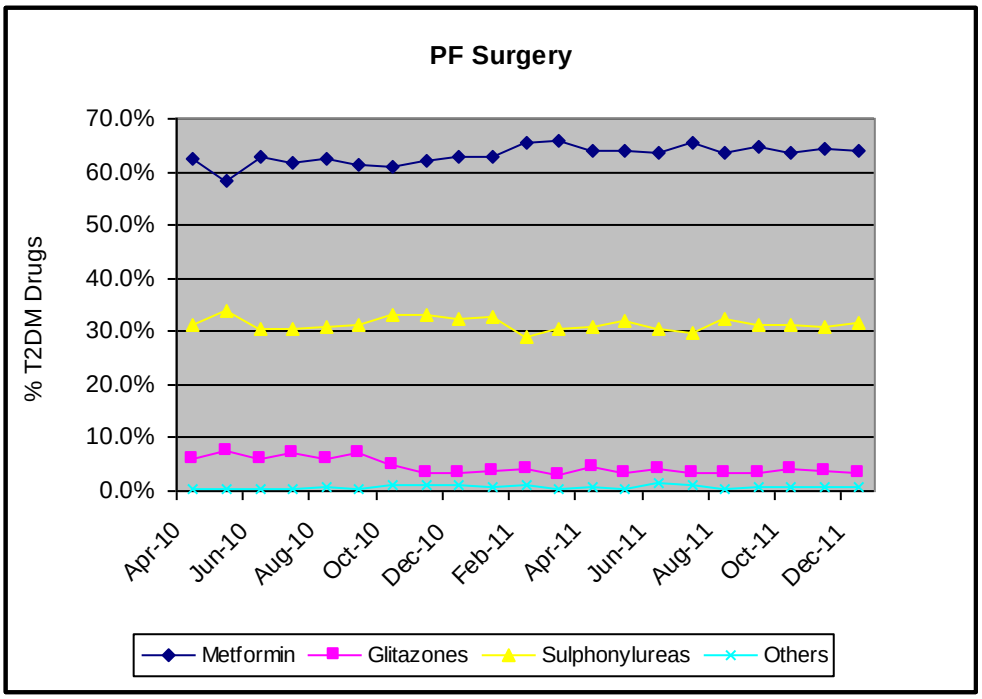


Graph 5.50. T2DM Drugs Trend Intervention Practices – HJ Centre

Drugs used in T2DM Prescribing Trend Data – Individual Intervention Practices

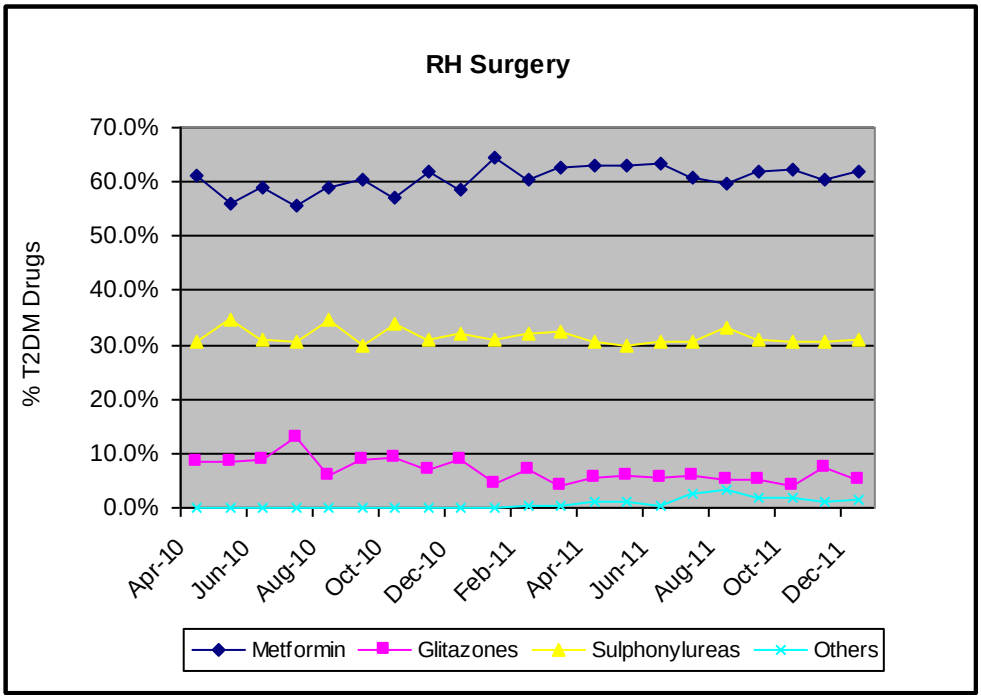


Graph 5.51. T2DM Drugs Trend Intervention Practices – PH Surgery

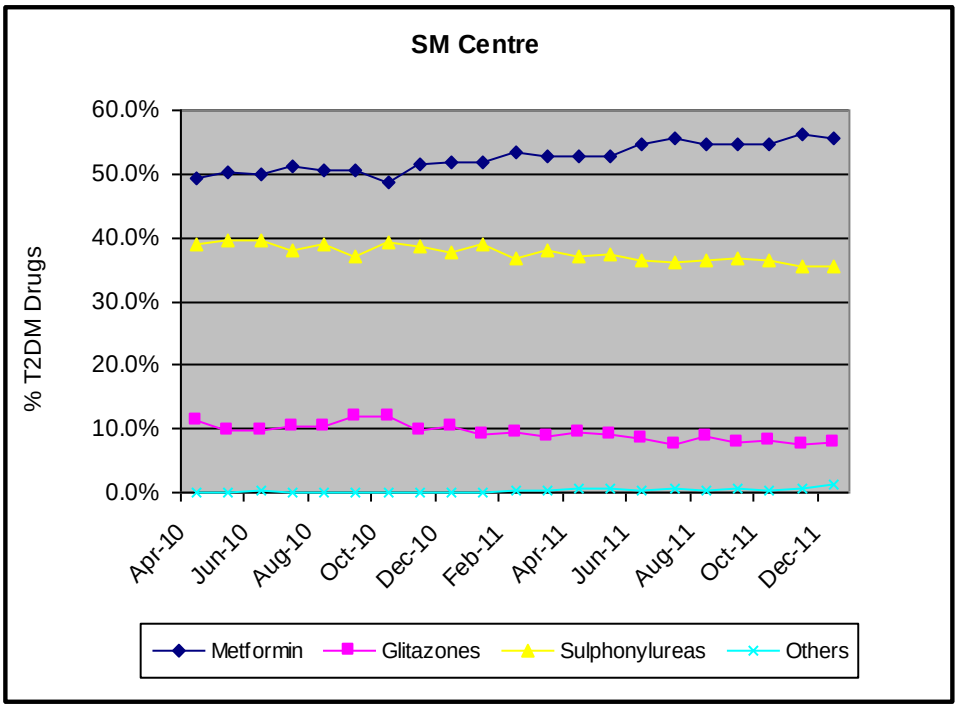


Graph 5.52. T2DM Drugs Trend Intervention Practices – PF Surgery

Drugs used in T2DM Prescribing Trend Data – Individual Intervention Practices

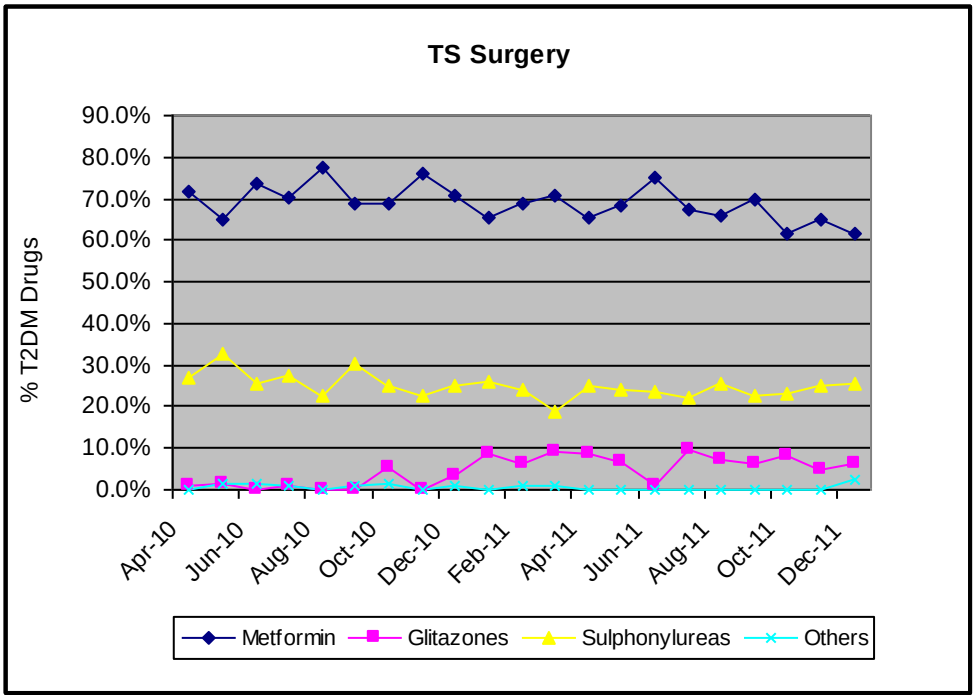


Graph 5.53. T2DM Drugs Trend Intervention Practices – RH Surgery

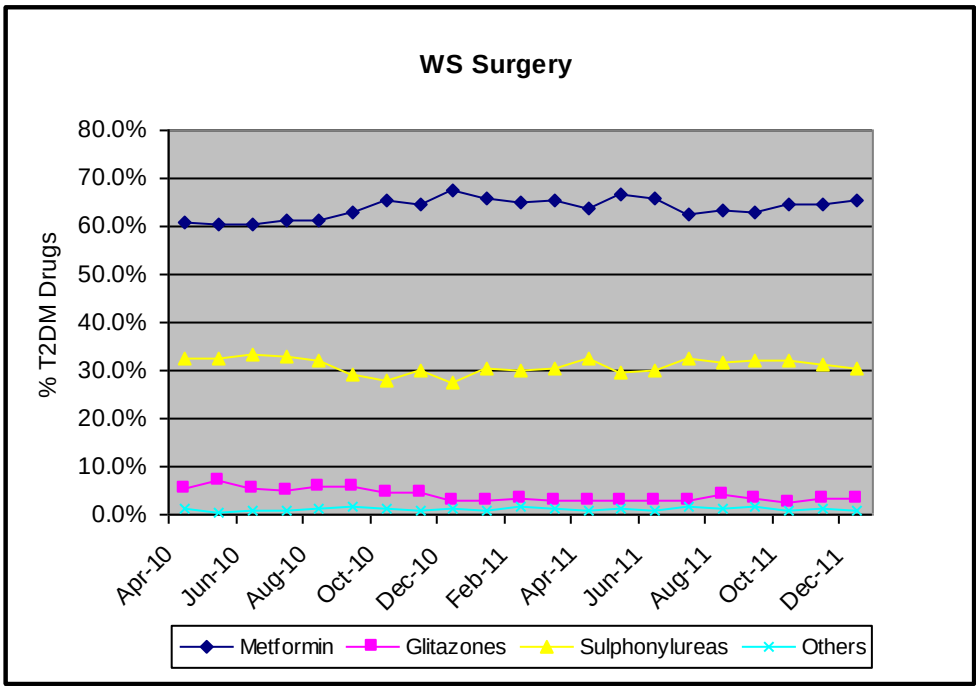


Graph 5.54. T2DM Drugs Trend Intervention Practices – SM Centre

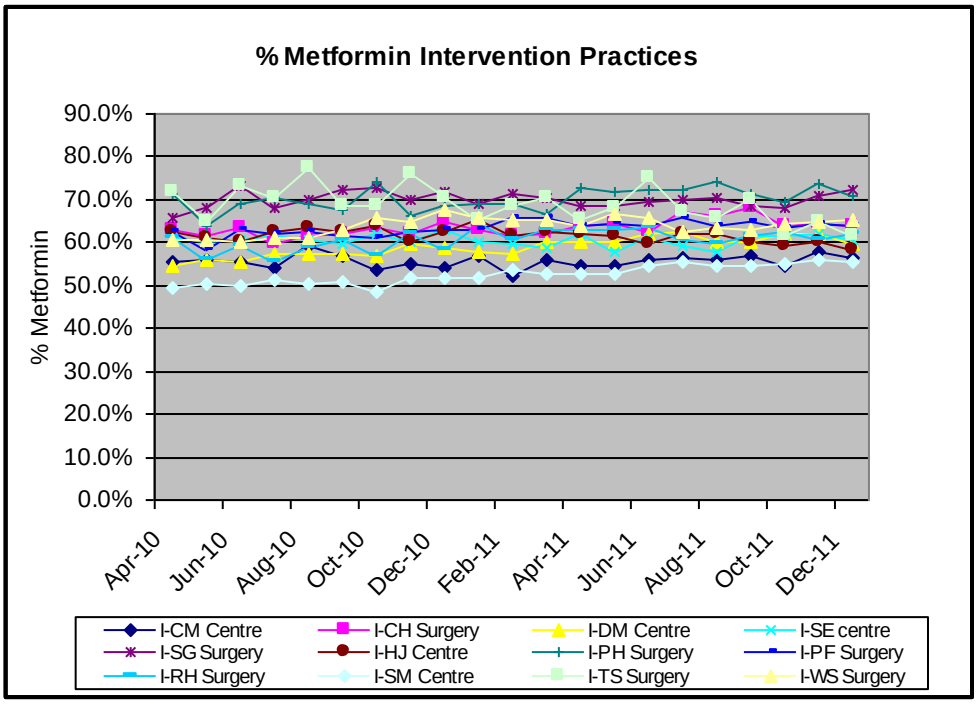
Drugs used in T2DM Prescribing Trend Data – Individual Intervention Practices



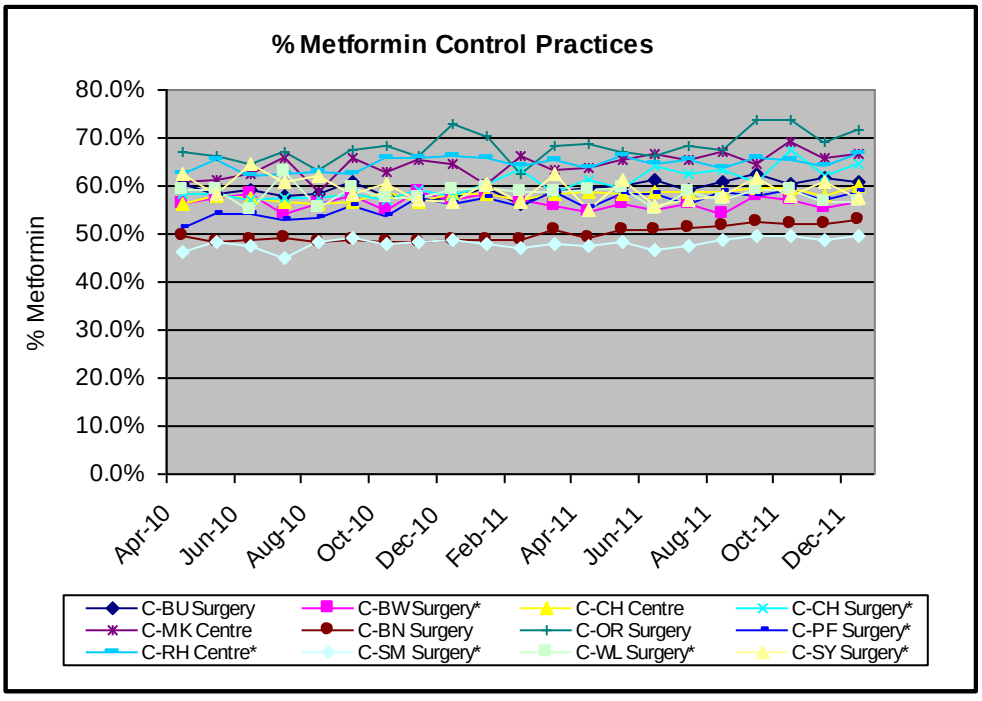
Graph 5.55. T2DM Drugs Trend Intervention Practices – TS Surgery



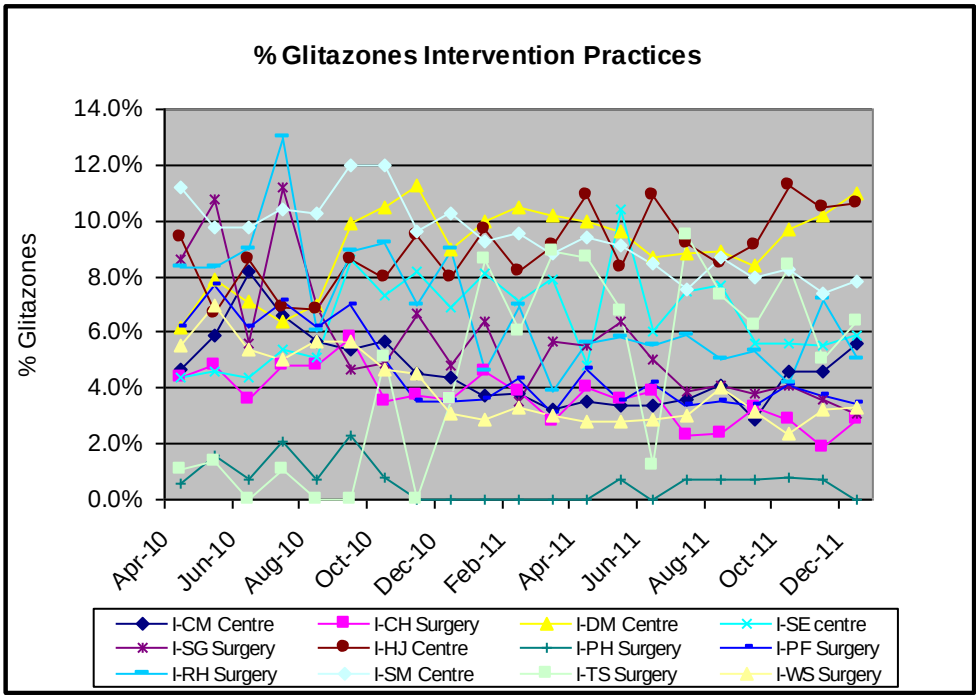
Graph 5.56. T2DM Drugs Trend Intervention Practices – WS Surgery



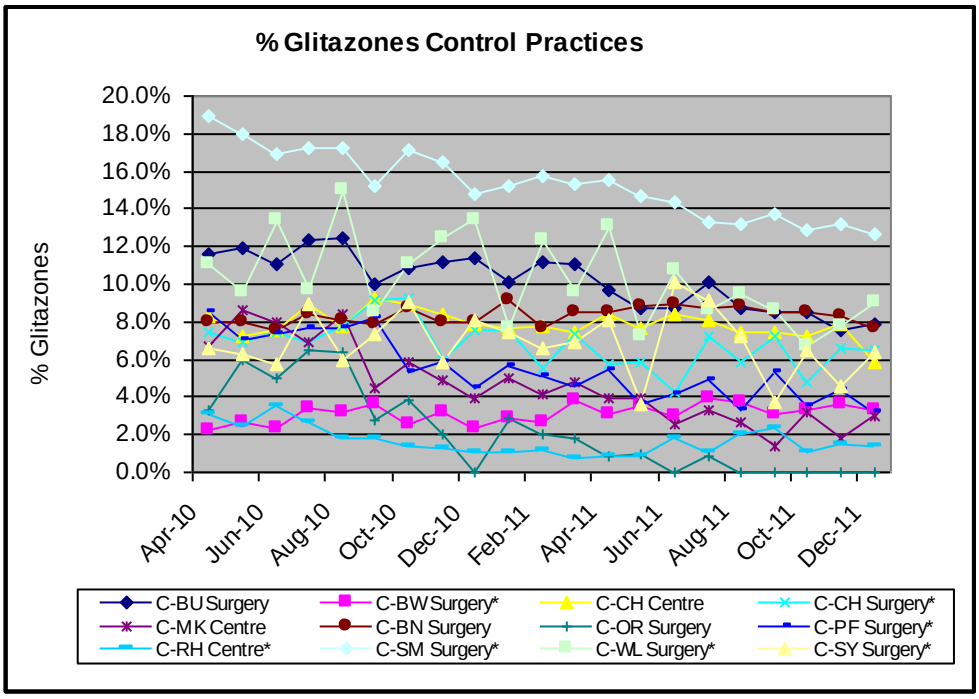
Graph 5.57. Metformin Trends - Intervention Practices



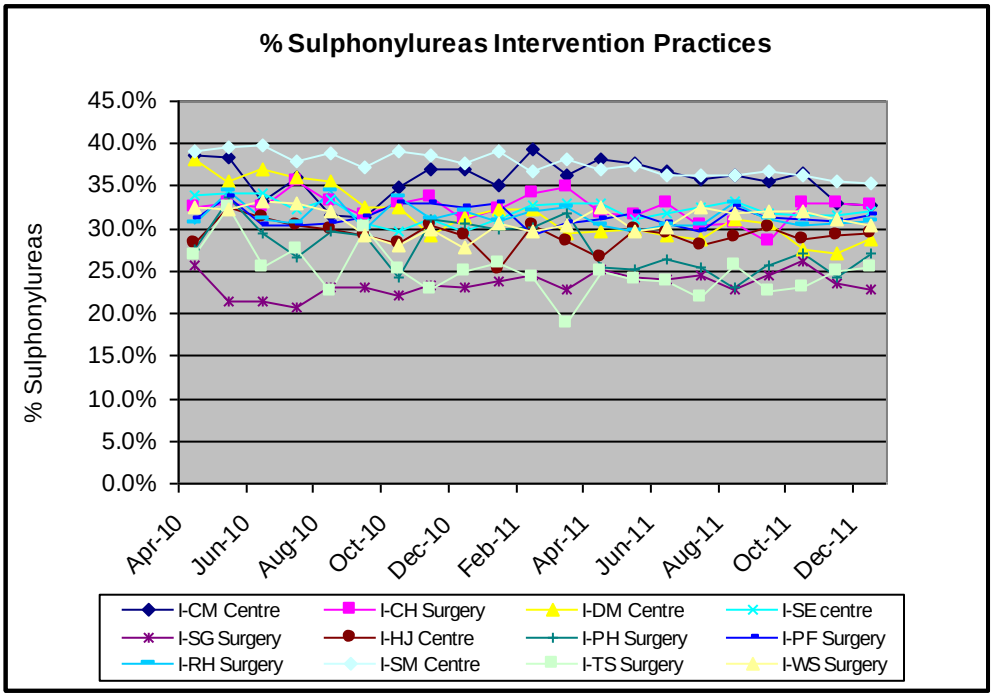
Graph 5.58. Metformin Trends - Control Practices



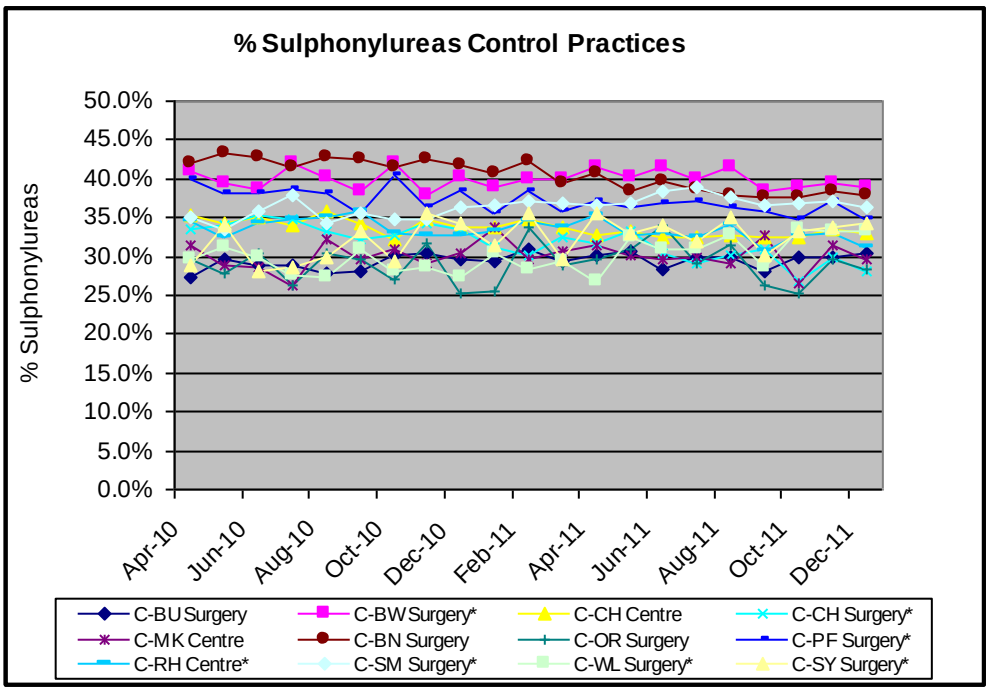
Graph 5.59. Glitazones Trends - Intervention Practices



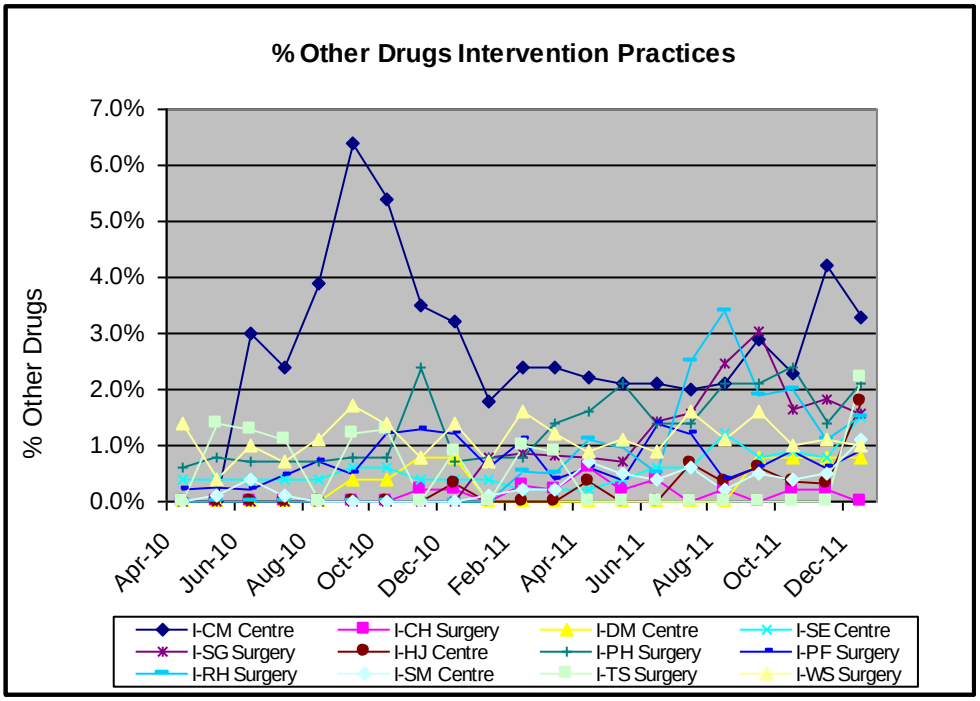
Graph 5.60. Glitazones Trends - Control Practices



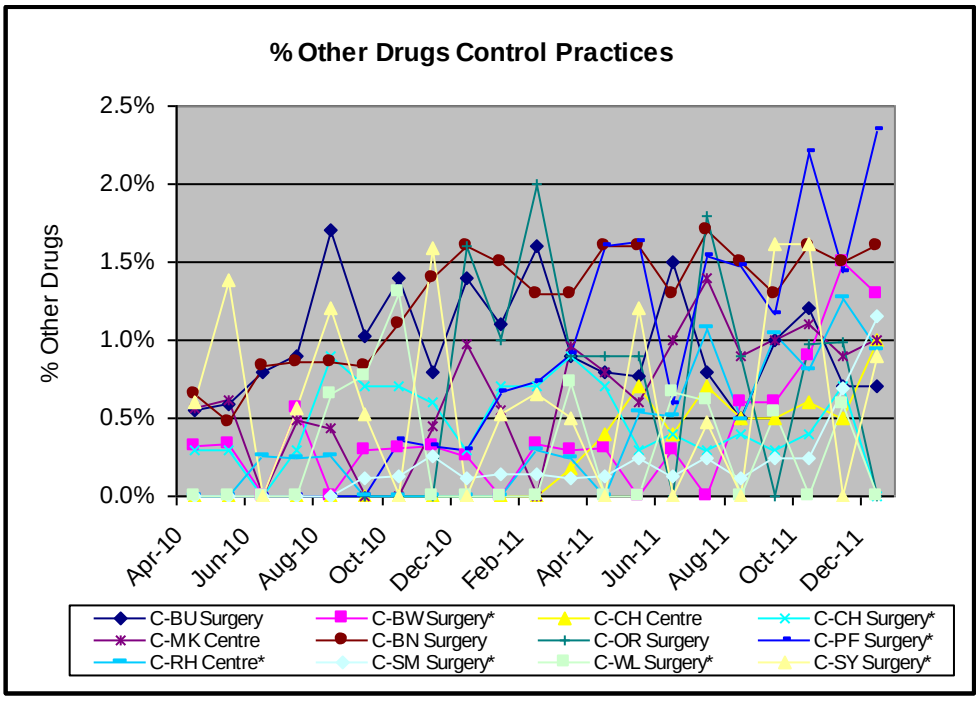
Graph 5.61. Sulphonylureas Trends - Intervention Practices



Graph 5.62. Sulphonylureas Trends - Control Practices



Graph 5.63. Other Drugs Trends - Intervention Practices



Graph 5.64. Other Drugs Trends - Control Practices

5.3.2 Drugs Used in Type 2 Diabetes (Cont)

Individual Practices (Graphs 5.33 to 5.56)

Overall there were no major shifts demonstrated in prescribing of drugs in T2DM between Intervention and Control practices. There were very slight increases in Metformin in several individual intervention and control practices

5.3.2.1 Aggregated Prescribing Trend Data

Aggregated data suggests that overall prescribing of metformin was slightly higher and within a narrower range in intervention practices, with a possible slight overall upward trend compared with control. (Graphs 5.57, 5.58)

There are no obvious differences in prescribing trends of glitazones or other anti-diabetic drugs in intervention practices compared with control. (Graphs 5.59-5.64).

5.4 Practice Data – Patient-Orientated Outcome Measures

5.4.1 Statistical Analysis

5.4.1.2 Non-Steroidal Anti-Inflammatory Drugs

Six different outcome measures were defined relating to patients receiving NSAIDs in each practice. The proportion of patients coded for each parameter was calculated at baseline and following completion of the intervention visits. Each outcome measure was based on the difference in post-intervention value compared with pre-intervention value. (Summarised in Table 5.17)

NSAIDs	Patient Orientated Outcome Measure

Risk Factor Measures	• Proportion of elderly patients (≥65) on NSAID
	• Proportion of patients with documented clinical risk factors (combined)
	  ○ Cardiovascular risk factors
	  ○ Gastrointestinal risk factors
	  ○ Cardio-renal Risk factors

Concomitant Medication Measures	• Proportion of patients on concomitant drugs
	  ○ Aspirin
	  ○ SSRI
	  ○ PPI (gastro-protection)

NSAIDs Prescribing Measures	• Proportion of patients on NSAIDs ○ NSAIDs (overall) as proportion of practice patient population

Table 5.17 Patient-Oriented Outcome Measures NSAIDs

Descriptive Statistics

Descriptive Statistics									
Measure (PreIntervention/Post Intervention Difference)	N	Minimum	Maximum	Mean	Std. Deviation	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
Overall NSAIDs	19	-0.4	0.2	-0.011	0.1912	-0.846	0.524	0.107	1.014
Over 65	19	-8	7.7	-0.545	4.2375	-0.131	0.524	-0.292	1.014
Total Risk	19	-8.1	4.8	-0.647	3.6234	-0.879	0.524	0.237	1.014
Proportion on PPI	19	-6	13.5	2.474	4.4237	0.493	0.524	1.172	1.014
Proportion on Aspirin	19	-6.3	3.4	-1.137	2.5303	-0.085	0.524	-0.258	1.014
Proportion on SSRI	19	-3.1	4.7	1.037	2.3005	-0.088	0.524	-0.641	1.014
Valid N (listwise)	17								

Table 5.18 Summary Descriptive Statistics – NSAID Patients

Summary descriptive statistics for the study sample (intervention and benchmark) practices are summarised in Table 5.18. The Statistic values referenced represent the difference between baseline value and post intervention value in the proportion of patients coded for each outcome measure/indicator

More detailed summary statistics for each NSAID indicator are provided in Appendix 40.

5.4.1.2.1 Testing for Significant Difference between Intervention and Control Groups

Assessing Normality

Histogram plots were produced in order to assess the normality of distribution of the data for each measure (Appendix 40). Normal Q-Q Plots were reviewed in conjunction to assess deviation of the scores from the straight line. Box Plots were also produced for each measure enabling identification of specific outliers.
Tests of normality were also produced as part of the data output.

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
Measure	Statistic	df	Sig.	Statistic	df	Sig.
Overall NSAIDs	0.206	19	0.033	0.869	19	0.014
Over 65	0.112	19	.200*	0.974	19	0.855
Total Risk	0.175	19	0.127	0.916	19	0.095
Proportion on PPI	0.124	19	.200*	0.964	19	0.655
Proportion on Aspirin	0.126	19	.200*	0.979	19	0.932
Proportion on SSRI	0.087	19	.200*	0.967	19	0.722

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

Table 5.19 Tests for Normality Summary for NSAID Patient-Orientated Outcome Measures

Review of the histograms and Normal Q-Q Plots indicated that the majority of the patient outcome indicators conformed with normal distribution of the data although normality tests suggested that data relating to overall NSAIDs, was not normally distributed. (Table 5.19)
NB: A non-significant result from normality tests (i.e.>0.05) indicates normality.

Independent t-tests were therefore performed in order to establish whether results for parametric data were statistically significant. Mann-Whitney U tests were also performed to establish if non-parametric data demonstrated statistical significance.

5.4.1.2.1.1 Independent Samples t-test (Parametric)

Independent Samples Test									
	Levene's Test for Equality of Variances		t-test for Equality of Means						
								95% Confidence Interval of the Difference	
Measure	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Overall NSAIDs	0.062	0.806	-0.926	17	0.367	-0.0845	0.0913	-0.2771	0.1081
Over 65	0.03	0.864	1.508	17	0.15	2.9378	1.9475	-1.1711	7.0466
Total Risk	0.601	0.449	-0.093	17	0.927	-0.1655	1.7728	-3.9057	3.5748
Proportion on PPI	0.003	0.956	0.614	17	0.547	1.3155	2.1412	-3.2021	5.8331
Proportion on Aspirin	0.231	0.637	-0.889	17	0.386	-1.0762	1.2105	-3.6301	1.4777
Proportion on SSRI	1.157	0.297	0.853	17	0.405	0.9405	1.1025	-1.3856	3.2665

NB: Significance values for Levin's test for equality of variances were > 0.05 for all indicators except ibuprofen, indicating that variances for the two groups are the same. Alternative t-value output figures from SPSS were therefore substituted for the ibuprofen output.

Table 5.20 Statistical Significance Summary - Independent t-Tests for NSAID Patient- Orientated Outcome Indicators

Parametric test results indicate that no statistically significant differences exist between intervention and benchmark practices for any of the patient-orientated outcome indicators relating to NSAIDs for the measures for which the data was regarded as normally distributed (or indeed the measures for which the data was not normally distributed) as none of the measures achieve significance value of < 0.05. (Table 5.20).

Outliers

It was noted that there were a limited number of outliers (cases with values well above or below the majority of other cases) for clinical risk factor, and PPI indicators. However, it was noted that 5% trimmed mean values for all of the indicators were very similar to the actual mean values, indicating that the outliers were not distorting the statistics or causing a problem in terms of the analysis.

5.4.1.2.1.2 Mann-Whitney U Tests (Non-Parametric)

Test Statistics[a]						
	Overall NSAIDs	**Over 65**	**Total Risk**	**PPI**	**Aspirin**	**SSRI**
Mann-Whitney U	29.5	27	41	37.5	31.5	35
Wilcoxon W	107.5	55	119	65.5	109.5	63
Z	-1.086	-1.268	-0.085	-0.38	-0.888	-0.592
Asymp. Sig. (2-tailed)	0.278	0.205	0.933	0.704	0.374	0.554
Exact Sig. [2*(1tailedSig.)]	.299[b]	.227[b]	.967[b]	.711[b]	.384[b]	.592[b]

a Grouping Variable:Group b Not corrected for ties.

Table 5.21 Test Statistics Summary Mann-Whitney U Tests NSAID Patient Outcome Measures

	Indicator Change Intervention Practices (n=12)		**Indicator Change Benchmark Practices (n=7)**		**Mann-Whitney U Tests**	
	Median	IQR	Median	IQR	Test Statistic	p-value
Overall NSAIDs	0.0	0.2	0.0	0.2	29.5	0.278
Over 65	0.469	6.1	-2.4	7.5	27.0	0.205
Total Risk	0.2	3.6	-0.4	7.5	41.0	0.933
PPI	2.6	5.1	0.5	6.3	37.5	0.704
Aspirin	-1.7	2.2	0.6	4.2	31.5	0.374
SSRI	1.1	3.6	0.6	5.2	35.0	0.554

* Significant at the 5% Level
** Significant at the 1% Level

Table 5.22 Statistical Significance Summary Mann-Whitney U Tests Patient Outcome Indicators

The results indicate that no statistically significant differences exists between intervention and benchmark practices for non-parametric indicators as none of the p-value figures reach statistical significance <0.05. (Tables 5.21 and 5.22).

Therefore, the null hypotheses that no difference exists for any of the NSAID patient outcome indicators between intervention and benchmark groups are retained.

5.4.1.3 Type 2 Diabetes

Thirteen different outcome measures were defined relating to patients diagnosed with T2DM in each practice. The proportion of patients coded for each parameter was calculated at baseline and following completion of the intervention visits. Each outcome measure was based on the difference in post-intervention value compared with pre-intervention value. (Summarised in Table 5.23)

Type 2 Diabetes	Patient Orientated Outcome Measure
Recommended Target Measures	Proportion of patients achieving: • Blood pressure (≤ 140/80mmHg) • Blood lipids (TC ≤ 5mmol/l) • HbA1c (≤ 7.5%) • HbA1c (≤ 9.0%) • ACR (men <2.5mg/mmol, women <3.5mg/mmol)
Prescribing Measures	• Proportion of patients on metformin, • Proportion of patients on lipid lowering therapy • Proportion of patients on aspirin • Proportion of patients prescribed a Renin-Angiotensin drug ○ Proportion of patients specifically prescribed an ACE-Inhibitor
Renal Care Measures	• Proportion of patients tested for microalbuminuria • Proportion of patients with microalbuminuria on a RAS drug • Proportion of patients with microalbuminuria attaining recommended BP target (≤ 130/80mmHg)

Table 5.23 Patient Oriented Outcome Measures T2DM

Descriptive Statistics

Summary descriptive statistics for the study sample (intervention and benchmark) practices are summarised in Table 5.24. The Statistic values referenced represent the difference between baseline value and post intervention value in the proportion of patients coded for each outcome measure/indicator

More detailed summary statistics for each T2DM indicator are provided in Appendix 41.

Descriptive Statistics									
	N	Minimum	Maximum	Mean	Std. Deviation	Skewness		Kurtosis	
Measure	Statistic	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
Metformin	19	-8.2	6.1	0.135	3.1749	-0.917	0.524	1.948	1.014
RAS Drug	19	-3.8	3.8	-0.437	1.7765	0.58	0.524	0.614	1.014
ACE-I	19	-5.1	4	0.163	2.251	-0.58	0.524	0.78	1.014
LLA	19	-8.2	5.8	-1.042	3.1565	-0.066	0.524	0.94	1.014
Aspirin	19	-16.6	0.9	-3.784	4.4873	-1.607	0.524	2.734	1.014
BP Target	19	-9.7	11.4	0.137	5.5696	0.312	0.524	-0.148	1.014
Cholesterol	17	-2.8	7	1.506	3.1364	0.412	0.55	-1.015	1.063
HbA1c (7.5%)	19	-9.3	5.5	-1.421	3.9973	0.051	0.524	-0.505	1.014
HbA1c (9.0%)	19	-10.3	5.7	-1.432	4.0594	-0.812	0.524	1.057	1.014
ACR Measured	19	-5	35.4	2.974	8.3952	3.491	0.524	13.794	1.014
M/A Detected	19	-5.4	7.9	0.253	2.8133	0.846	0.524	2.352	1.014
m/a on RAS	19	-18.1	47.1	3.842	15.7286	1.489	0.524	2.549	1.014
m/a BP target	19	-14.1	11.5	-1.526	8.8618	-0.03	0.524	-1.478	1.014
Valid N (listwise)	17								

Table 5.24 Summary Descriptive Statistics – T2DM Patients

5.4.1.3.1 Testing for Significant Difference between Intervention and Control Groups

Assessing Normality

Histogram plots were produced in order to assess the normality of distribution of the data for each measure (Appendix 41). Normal Q-Q Plots were reviewed in conjunction to assess deviation of the scores from the straight line. Box Plots were also produced for each measure enabling identification of specific outliers.
Tests of normality were also produced as part of the data output.

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
Measure	Statistic	df	Sig.	Statistic	df	Sig.
Metformin	0.145	19	.200*	0.934	19	0.208
RAS Drug	0.172	19	0.142	0.96	19	0.574
ACE-I	0.155	19	.200*	0.946	19	0.34
LLA	0.12	19	.200*	0.986	19	0.988
Aspirin	0.173	19	0.139	0.841	19	0.005
BP Target	0.141	19	.200*	0.97	19	0.771
Cholesterol	0.177	17	0.16	0.939	17	0.303
HbA1c (7.5%)	0.112	19	.200*	0.967	19	0.722
HbA1c (9.0%)	0.148	19	.200*	0.923	19	0.129
ACR Measured	0.285	19	0.0	0.57	19	0.0
M/A Detected	0.195	19	0.054	0.927	19	0.15
m/a on RAS	0.217	19	0.019	0.86	19	0.01
m/a BP target	0.174	19	0.134	0.917	19	0.1

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

Table 5.25 Tests for Normality Summary for T2DM Patient Outcome Measures

Review of the histograms and Normal Q-Q Plots indicated that the majority of the patient outcome indicators conformed with normal distribution of the data although sample sizes were relatively small. Exceptions appeared to relate mainly to renal outcome indicators (proportion of patients with ACR measured, patients with microalbuminuria on a RAS Drug and proportion of patients with microalbuminuria reaching recommended BP target).

Normality tests, in particular Shapiro-Wilk (more appropriate for smaller sample sizes) indicated that data may not be normally distributed in two of the renal indicators (ACR measured, m/a on RAS) and for proportion of patients on aspirin. (Table 5.25)
NB: A non-significant result from normality tests (i.e.>0.05) indicates normality

Independent t-tests were therefore performed in order to establish whether results for parametric data were statistically significant. Mann-Whitney U tests were also performed to establish if non-parametric data demonstrated statistical significance.

Outliers

It was noted that there were a limited number of outliers (cases with values well above or below the majority of other cases) for various indicators. However, it was noted that 5% trimmed mean values for all of the indicators were relatively close to the actual mean values, indicating that the outliers were not distorting the statistics or causing a problem in terms of the analysis.

5.4.1.3.1.1 Independent Samples T-tests

Independent Samples Test									
	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Metformin	2.38	0.141	2.189	17	0.043*	3.0037	1.3724	0.1083	5.8992
RAS Drug	1.939	0.182	2.309	17	0.034*	1.7512	0.7586	0.1508	3.3516
ACE-I	1.218	0.285	1.397	17	0.181	1.4571	1.0434	-0.7442	3.6584
LLA	1.934	0.182	0.221	17	0.828	0.3405	1.5425	-2.914	3.595
Aspirin	3.144	0.094	0.301	17	0.767	0.6583	2.1902	-3.9626	5.2792
BP Target	2.604	0.125	-0.311	17	0.759	-0.8464	2.7179	-6.5807	4.8879
Cholesterol	0.159	0.695	1.361	15	0.194	2.05	1.506	-1.16	5.26
HbA1c (7.5%)	0.696	0.416	3.317	17	0.004**	5.056	1.5242	1.8402	8.2717
HbA1c (9.0%)	0.004	0.953	2.239	17	0.039*	3.9083	1.7459	0.2248	7.5918
ACR Measured	1.662	0.215	0.992	17	0.335	3.9619	3.9945	-4.4658	12.3896
M/A Detected	1.145	0.3	0.126	17	0.901	0.1738	1.3762	-2.7296	3.0772
m/a on RAS	0.522	0.48	1.216	17	0.241	8.9786	7.3828	-6.5979	24.555
m/a BP target	0.527	0.478	-0.281	17	0.782	-1.2179	4.3267	-10.3465	7.9107

NB: Significance values for Levin's test for equality of variances are all > 0.05 indicating that variances for the two groups are the same.

* Significant at the 5% Level

** Significant at the 1% Level

Table 5.26 Statistical Significance Summary - Independent Tests for T2DM Patient Outcome Indicators

The results demonstrate that statistically significant differences exist between intervention and benchmark practices for four indicators. They indicate a relative increase in the proportion of patients being prescribed both metformin and renin-angiotensin drugs, in the intervention group compared with the benchmark group over the intervention period. There is also a statistically significant difference indicating a relative increase in proportion of patients achieving both HbA1c targets (7.5%, 9.0%) at study completion in the intervention group compared with benchmark practices.

Results are summarised in Table 5.26 and as follows:

- Proportion of patients prescribed metformin ($p<0.05$)
- Proportion of patients prescribed a Renin-Angiotensin drug ($p<0.05$)
- Proportion of patients achieving HbA1c target ≤ 7.5% ($p<0.01$)
- Proportion of patients achieving HbA1c target ≤ 9.0% ($p<0.05$)

Therefore, the null hypotheses that no difference exists in achievement of patient-oriented outcomes between intervention and control groups are rejected. The null hypothesis that no difference exists in achievement of patient clinical outcomes (HbA1c target) between intervention and control groups is also rejected.

5.4.1.3.1.2 Mann-Whitney U Tests

Test Statistics[a]					
	Metformin	RAS	ACE-I	LLA	Aspirin
Mann-Whitney U	22.5	17.5	36.5	40.5	25
Wilcoxon W	50.5	45.5	64.5	68.5	53
Z	-1.649	-2.072	-0.466	-0.127	-1.437
Asymp. Sig. (2-tailed)	0.099	0.038	0.641	0.899	0.151
Exact Sig. [2*(1-tailed Sig.)]	.100[b]	.036[b]	.650[b]	.902[b]	.167[b]

a Grouping Variable: Group
b Not corrected for ties.

Test Statistics[a]								
	BP Target	Cholest	HbA1c (<7.5%)	HbA1c (<9.0%)	ACR Measured	M/A Detected	m/a RAS	m/a BP
Mann-Whitney U	36	21.5	12	9	23.5	41.5	25	37.5
Wilcoxon W	114	49.5	40	37	51.5	69.5	53	115.5
Z	-0.507	-1.318	-2.537	-2.79	-1.567	-0.042	-1.437	-0.381
Asymp. Sig. (2-tailed)	0.612	0.187	0.011	0.005	0.117	0.966	0.151	0.703
Exact Sig. [2*(1-tailed Sig.)]	.650[b]	.193[b]	.010[b]	.004[b]	.120[b]	.967[b]	.167[b]	.711[b]

a Grouping Variable: Group
b Not corrected for ties.

Table 5.27 Test Statistics Summary Mann-Whitney U Tests T2DM Patient Outcome Measures

	Indicator Change Intervention Practices (n=12)		**Indicator Change Benchmark Practices (n=7)**		**Mann-Whitney U Tests**	
	Median	IQR	Median	IQR	Test Statistic	p-value
Metformin	1.05	3.0	-1.5	7.1	22.5	0.099
RAS Drug	0.35	2.8	-1.5	1.7	17.5	0.038*
ACE-I	0.5	3.8	0.7	4.8	36.5	0.641
LLA	-0.7	4.2	-1.1	3.3	40.5	0.899
Aspirin	-1.05	5.7	-4.5	4.3	25.0	0.151
BP Target	-1.45	9.8	-0.1	6.2	36.0	0.612
Cholesterol	2.2	5.4	-0.6	4.7	21.5	0.187
HbA1c (7.5%)	1.25	5.2	-5.2	4.1	12.0	0.011*
HbA1c (9.0%)	0.2	2.6	-2.9	4.6	9.9	0.005**
ACR Measured	1.5	6.4	-0.8	3.0	23.5	0.117
M/A Detected	-0.3	4.2	-0.5	2.7	41.5	0.966
m/a on RAS	2.05	14.0	-0.1	15.1	25.0	0.151
m/a BP target	-1.25	18.7	-6.2	19.3	37.5	0.703

* Significant at the 5% Level
** Significant at the 1% Level

Table 5.28 Statistical Significance Summary Mann-Whitney U Tests T2DM Patient Outcome Indicators

The Mann-Whitney U tests do not suggest that there are additional indicators demonstrating statistical significance. (Tables 5.27 and 5.28). However, they do support the results of independent t-tests in that prescribing of RAS drugs and that both HbA1c target indicators demonstrate statistical significance.

5.4.2 Comparison Between Intervention and Benchmark Group Practices

Data from non-intervention practices provided a benchmark by which to compare the intervention practice group data and to also establish whether there were any underlying influences on prescribing affecting all practices in the PCT, which may have affected achievement of outcome targets.

It is acknowledged that the comparison reported here is a relatively crude one. However the comparison is made to detect and identify any differences or differing trends in the intervention group practices (which may be attributable to the intervention) compared with non-intervention practices.

5.4.2.1 Type 2 Diabetes

Summary data for the patient outcome-orientated prescribing indicators, clinical outcomes and renal outcomes at practice level (summarised in Table 5.23) are presented in tabular form in the following section. Significant post-intervention shifts from baseline are highlighted in green.

5.4.2.1.1 Prescribing Outcome Indicators

Summarised in Table 5.29

5.4.2.1.1.1 Metformin

The results in the benchmark group indicate that two practices (CH and PF) may have increased the proportion of patients who have received metformin. However, four practices have a relative decrease in metformin prescribing (one has no change) suggesting a trend towards a relative decrease.

In all but two practices (PF, WS), in the intervention group the trend is towards an increase in metformin use. One other practice shows no change (HJC), however, this practice demonstrates the highest metformin prescribing at baseline suggesting limited capacity to maximise further.

5.4.2.1.1.2 Renin-Angiotensin Drugs

Overall RAS Drugs

All of the practices in the Benchmark Group indicate a relative decrease in prescribing of RAS drugs. For two practices (CH, PF) the figure is marginal.

In the intervention group, seven of the twelve practices demonstrate a relative increase in overall prescribing of RAS drugs in patients with T2DM, suggesting an overall increase during the intervention period (as promoted during the intervention).

	Percentage of Patients														
	Metformin			RAS Drugs			ACE-I / RAS Drugs			LLA			Aspirin		
Practice	Pre	Post	% Diff	Pre	Post	% Diff	Pre	Post	% Diff	Pre	Post	% Diff	Pre	Post	% Diff
BENCHMARK															
BW Surgery	63.1	63.3	0.2	56.2	54.7	-1.5	79.2	74.1	-5.1	74.8	73.7	-1.1	46.4	41.9	-4.5
CH Surgery	66.8	69.3	2.5	59.0	58.7	-0.3	69.0	70.0	1.0	76.0	75.1	-0.9	49.0	42.6	-6.4
PF Surgery	61.9	63.8	1.9	63.8	63.5	-0.3	64.0	63.7	-0.3	76.7	78.4	1.7	40.1	35.1	-5.0
RH Centre	65.7	57.5	-8.2	57.2	55.2	-2.0	77.2	78.7	1.5	77.5	75.6	-1.9	46.9	43.4	-3.5
SM Surgery	62.1	56.9	-5.2	61.0	59.8	-1.2	75.6	76.3	0.7	78.7	75.9	-2.8	46.7	39.7	-7.0
WL Surgery	72.8	71.3	-1.5	61.8	58.0	-3.8	82.1	78.3	-3.8	73.5	69.2	-4.3	30.1	28.0	-2.1
SY Surgery	73.4	71.4	-2.0	60.4	58.7	-1.7	82.8	83.5	0.7	71.4	71.9	0.5	44.8	43.9	-0.9
INTERVENTION															
CM Centre	59.9	61.6	1.7	57.1	57.8	0.7	62.4	66.4	4.0	70.1	73.5	3.4	41.8	29.9	-11.9
CH Surgery	66.0	68.3	2.3	59.8	60.3	0.5	73.8	77.2	3.4	72.0	71.8	-0.2	43.1	41.8	-1.3
DM Centre	60.6	63.6	3.0	58.9	60.3	1.4	74.8	75.2	0.4	66.5	64.4	-2.1	47.9	46.2	-1.7
SE Centre	60.4	60.8	0.4	62.2	62.4	0.2	73.3	73.9	0.6	75.7	76.7	1.0	47.1	46.5	-0.6
SG Surgery	65.0	66.2	1.2	67.5	66.2	-1.3	81.9	84.9	3.0	68.3	63.1	-5.2	35.0	35.4	0.4
HJ Centre	75.7	75.4	-0.3	65.6	67.7	2.1	75.6	75.8	0.2	76.5	78.0	1.5	44.5	43.7	-0.8
PH Surgery	58.4	61.3	2.9	55.2	56.5	1.3	77.6	78.9	1.3	77.3	74.4	-2.9	29.2	22.6	-6.6
PF Surgery	66.8	65.4	-1.4	64.2	63.1	-1.1	76.1	75.8	-0.3	79.4	78.2	-1.2	51.9	35.3	-16.6
RH Surgery	66.2	72.3	6.1	60.1	63.9	3.8	86.7	85.1	-1.6	66.5	72.3	5.8	33.8	33.6	-0.2
SM Centre	61.9	62.8	0.9	68.2	66.8	-1.4	80.9	81.5	0.6	77.9	75.1	-2.8	57.3	53.5	-3.8
TS Surgery	66.1	66.1	0.0	55.4	53.9	-1.5	62.9	61.3	-1.6	82.1	73.9	-8.2	31.3	32.2	0.9
WS surgery	59.8	58.0	-1.8	60.5	58.3	-2.2	75.8	74.2	-1.6	68.1	68.0	-0.1	42.9	42.6	-0.3

Table 5.29 Movement in Prescribing of Patient-Orientated Prescribing Outcome Indicators from Baseline to Post Intervention

Proportion of ACE-I as a Total of RAS Drug Prescribing

The benchmark group shows a range of prescribing of ACE-I and A-II-A (two practices (WL and SY) already have high baseline prescribing of ACE-Is. Overall there is a mixture of relative increase, relative decrease and marginal shifts in proportions of drug in each class with no major trends apparent.

Eight practices in the intervention group show a relative increase in ACE-I. Two of these, SMC and SG, also had very high baseline prescribing rates (as did RH). Otherwise, intervention practice trends are towards a relative increase. Three practices, CMC, CH and SG have relatively higher proportionate increases of ACE-I prescribing).

5.4.2.1.1.3 Lipid Lowering Agents (Statins)

The benchmark group shows a range of relative positive and negative variation. No obvious trend is apparent.

Similarly, the Intervention group has a range of relative differences. Two practices (SG and TS) have relatively large decreases (5.2% and 8.2 %) however only represented seven and two patients respectively as practice T2DM populations were relatively small. No major conclusions can be drawn from these figures although it is believed that statin prescribing in T2DM may have been managed within overall practice hypercholesterolemia management. Also, practice visit discussions generally focussed on management of blood pressure rather than blood lipids, because of its higher impact in managing cardiovascular risk.

5.4.2.1.1.4 Aspirin/Antiplatelet

All Practices in the Benchmark group demonstrate a trend towards a decrease in prescribing of aspirin or other antiplatelet drug. Similarly, all but two intervention practices demonstrated a trend towards decreased prescribing of aspirin/antiplatelet,

The PCT wide trend in reduction of aspirin/antiplatelet is believed to relate to widely published evidence for lack of benefit of aspirin in primary prevention of cardiovascular events compared with evidence in secondary prevention during the intervention period. Several practices actively stopped initiation of aspirin for primary prevention during this period.

5.4.2.1.2 Patient Clinical Outcome Indicators

Summarised in Table 5.30

5.4.2.1.2 .1 HbA1c

For both HbA1c targets the difference for all benchmark practices demonstrated negative values, indicating a relative reduction in achievement of the targets.

In the intervention group, seven intervention practices achieved greater proportion of patients achieving the 7.5% target and seven practices achieved higher proportion of patients with HbA1c less than 9.0%, reflecting results demonstrated in the statistical analysis that more patients in intervention practices were achieving reductions in HbA1c.

5.4.2.1.2 .2 Blood Pressure

Benchmark figures do not suggest any clear trend in increase or decrease in proportion of patients with T2DM meeting recommended blood pressure target (140/80mmHg) with figures ranging between negative and positive values. One practice (RMC), indicates a moderate increase (6.3%).

Similarly, there is no obvious trend in terms of increase or decrease in achievement of targets in the intervention group. However, two practices (DMC, TS) show large increases in proportion of patients achieving BP target of 9.5% and 11.4% respectively, with two further practices (CH, SG) showing moderate increases (4.9%, 4.6%).

5.4.2.1.2 .3 Blood lipids

Benchmark practice figures range from negative to positive values and no obvious trend is demonstrated. One large practice (SM) suggests a moderate increase.

Similarly, intervention practice values range from negative to positive values. Three practices have values which may suggest moderate increases. There is no major shift in increased proportion of patients achieving total cholesterol targets (5mmol/l) although results suggest a general trend to better achievement of target in the intervention group.

	Percentage of Patients											
	HbA1c (≤ 7.5%)			HbA1c (≤ 9.0%)			Blood Pressure (≤140/80mmHg)			Total Cholesterol (≤5mmol/l)		
Practice	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**
BENCHMARK												
BW Surgery	65.0	59.5	-5.5	91.6	81.3	-10.3	81.4	78.2	-3.2	51.5	50.9	-0.6
CH Surgery	61.6	61.0	-0.6	87.4	86.1	-1.3	51.3	52.4	1.1	43.8	43.6	-0.2
PF Surgery	66.5	64.9	-1.6	87.5	86.2	-1.3	77.8	76.2	-1.6	41.2	39.4	-1.8
RH Centre	57.2	52.0	-5.2	81.9	79.6	-2.3	69.3	75.6	6.3	39.6	38.5	-1.1
SM Surgery	66.1	60.4	-5.7	90.3	87.4	-2.9	71.6	71.5	-0.1	40.3	45.7	5.4
WL Surgery	75.0	65.7	-9.3	91.9	86.0	-5.9	44.1	48.3	4.2	41.2	44.1	2.9
SY Surgery	65.5	61.2	-4.3	85.9	82.1	-3.8	50.0	48.0	-2.0	50.5	48.0	-2.5
INTERVENTION												
CM Centre	53.1	58.3	5.2	80.8	82.0	1.2	67.8	64.0	-3.8	35.6	N/A	N/A
CH Surgery	57.3	58.6	1.3	81.6	81.7	0.1	62.1	67.0	4.9	32.9	37.4	4.5
DM Centre	65.3	66.8	1.5	86.4	85.8	-0.6	86.9	96.4	9.5	26.7	27.5	0.8
SE Centre	54.5	60.0	5.5	81.0	84.9	3.9	66.2	56.5	-9.7	40.9	42.9	2.0
SG Surgery	52.0	50.0	-2.0	90.2	80.0	-10.2	43.1	47.7	4.6	37.4	34.6	-2.8
HJ Centre	47.7	48.9	1.2	77.1	76.7	-0.4	62.4	54.0	-8.4	45.6	45.0	-0.6
PH Surgery	59.7	57.7	-2.0	81.2	86.9	5.7	64.3	64.3	0.0	32.5	36.3	3.8
PF Surgery	52.9	56.5	3.6	78.4	78.9	0.5	48.8	46.5	-2.3	42.0	41.7	-0.3
RH Surgery	63.9	61.7	-2.2	81.0	80.7	-0.3	53.6	48.2	-5.4	30.4	32.8	2.4
SM Centre	65.5	66.9	1.4	81.9	84.2	2.3	81.2	79.4	-1.8	N/A	N/A	N/A
TS Surgery	73.2	70.4	-2.8	92.0	89.6	-2.4	61.6	73.0	11.4	32.1	39.1	7.0
WS surgery	63.1	57.7	-5.4	89.0	89.3	0.3	41.2	40.1	-1.1	59.8	66.5	6.7

Table 5.30 Movement in Achievement of Patient Outcome Indicators from Baseline to Post Intervention

5.4.2.1.3 Patient Renal Clinical Outcome Indicators

Summarised in Table 5.31

- Proportion of patients with ACR measured
- Proportion with documented microalbuminuria
- Proportion with documented microalbuminuria prescribed a RAS drug
- Proportion with microalbuminuria meeting recommended BP target (≤130/80mmHg)

5.4.2.1.3.1 ACR Measured

There are no major shifts in proportion of patients having ACR measured at pre-intervention and post-intervention time points in Benchmark or Intervention practices, except for DMC (Intervention) which shows an increase of 35.4% of patients being tested for microalbuminuria. However, the general trend appears to be an increase in proportion of patients having ACR measured in intervention practices.

5.4.2.1.3.2 Microalbuminuria Detected

There are no major differences in proportion of patients with microalbuminuria detected in Benchmark or Intervention practices, except for TS (7.9% increase).

5.4.2.1.3.3 Proportion of Patients on RAS Drug and Achievement of BP Targets

Only one (small) Benchmark practice (PF,) shows a relatively substantial increase in the number of patients with microalbuminuria on a RAS drug (21.1%). There is however a relative reduction (6.3%) in proportion of patients meeting the recommended blood pressure target. One other (small) practice (BW) indicates a marginal increase in patients on a RAS drug (two patients only). However, there is a slight increase (eight patients) in patients achieving the recommended BP target. All other benchmark practices show a relative reduction in the number of patients with microalbuminuria on a RAS drug ranging from -0.5% to -18.1%.

Other practices (except RMC and BW) also show a relative reduction in proportion of patients achieving the recommended blood pressure target. There are no practices which indicate an overall improvement in management of renal outcomes in the benchmark group.

In contrast, six practices in the intervention group, (CH, CMC, SG, PH, RH and WS) demonstrate an overall improvement on the management of renal care in the T2DM population. All of them show an increase in prescribing of RAS drugs ranging from 0.2% to 34.2%. Five of them show a significant increase in achievement of blood pressure target ranging from 2.7-10.1% in patients with microalbuminuria. Three further practices (DMC, HJC, TS) all also demonstrate an increase prescribing of RAS drugs in microalbuminuria. The percentage figures may suggest that these practices have a relative reduction in number reaching recommended BP targets. However, the figures reflect differences of only one or two patients per practice. Additionally, achievement of BP targets in a group of patients with newly diagnosed microalbuminuria would take time to achieve.

	Percentage of Patients											
	ACR Measured			Microalbuminuria Detected			Patients with m/a on RAS			Patients with m/a BP Target (≤130/80mmHg)		
Practice	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**
BENCHMARK												
BW Surgery	83.2	82.0	-1.2	25.9	25.7	-0.2	55.9	57.4	1.5	50.8	62.3	11.5
CH Surgery	83.5	85.4	1.9	28.4	27.4	-1.0	66.3	52.7	-13.6	32.6	38.7	6.1
PF Surgery	78.2	83.7	5.5	20.9	20.3	-0.6	64.3	85.4	21.1	50.0	43.8	-6.2
RH Centre	91.3	90.5	-0.8	26.2	24.3	-1.9	71.7	53.6	-18.1	41.4	51.5	10.1
SM Surgery	84.0	82.9	-1.1	23.3	25.0	1.7	69.6	69.1	-0.5	59.2	50.0	-9.2
WL Surgery	88.2	87.4	-0.8	31.7	35.2	3.5	73.7	72.7	-1.0	47.4	40.9	-6.5
SY Surgery	84.9	84.7	-0.2	27.6	27.1	-0.5	80.0	77.8	-2.2	33.3	22.2	-11.1
INTERVENTION												
CM Centre	92.7	91.9	-0.8	21.3	21.1	-0.2	42.9	77.1	34.2	40.0	46.3	6.3
CH Surgery	89.4	94.7	5.3	22.1	25.3	3.2	71.6	71.8	0.2	43.1	45.8	2.7
DM Centre	59.3	94.7	35.4	35.7	30.3	-5.4	30.0	77.1	47.1	60.0	46.5	-13.5
SE Centre	91.4	91.6	0.2	18.4	16.0	-2.4	72.4	72.2	-0.2	69.7	55.6	-14.1
SG Surgery	90.2	90.8	0.6	23.4	22.9	-0.5	65.4	70.4	5.0	26.9	37.0	10.1
HJ Centre	28.0	29.9	1.9	59.0	61.9	2.9	72.6	75.7	3.1	43.5	34.3	-9.2
PH Surgery	90.9	93.5	2.6	15.7	15.3	-0.4	68.2	79.2	11.0	22.7	29.2	6.5
PF Surgery	89.3	88.6	-0.7	20.7	18.8	-1.9	87.4	82.1	-5.3	32.6	31.1	-1.5
RH Surgery	76.0	82.1	6.1	26.5	27.1	0.6	73.6	80.3	6.7	32.1	31.1	-1.0
SM Centre	92.7	87.7	-5.0	24.5	23.3	-1.2	87.7	80.8	-6.9	55.6	53.5	-2.1
TS Surgery	91.1	92.2	1.1	15.7	23.6	7.9	75.0	76.0	1.0	50.0	36.0	-14.0
WS surgery	84.1	90.6	6.5	15.4	16.6	1.2	87.2	77.1	-10.1	23.1	29.2	6.1

Table 5.31 Movement in Patient Outcome Indicators from Baseline to Post Intervention

The remaining three practices in the intervention group, (SE, PF, SMC) show no improvement in any of the renal outcome measures. Interestingly, these practices all received the intervention from the same pharmacist. Visit reports for these practices indicated that renal outcomes were not covered during the intervention visits whereas all other pharmacists reviewed renal care with their practices at some time during the intervention period.

The overall trends for the patient-orientated T2DM outcomes discussed here (improvements highlighted in green) are suggestive of better management of aspects of diabetes in the intervention group practices compared with benchmark.

5.4.2.2 Non-Steroidal Anti-inflammatory Drugs

Summary data for patient-orientated clinical outcomes (risk factors) and for patient-orientated prescribing indicators (concomitant medication), (Summarised in Table 5.17) are presented in tabular form in the following section. Significant post-intervention shifts from baseline are highlighted in green.

5.4.2.2.1 Proportion of Practice Population on NSAID

Summarised in Table 5.32

Proportion of patients on NSAIDs as a total practice population ranged from 1.4% (WL) to 3.2% (SM) at Baseline in benchmark practices. During the intervention period, only one practice (RMC) slightly reduced proportion of patients on NSAIDs by 0.3%.

Proportion of patients on NSAIDs in the intervention group, ranged from 0.8% (TS) to 4.5% (SE) at Baseline. During the intervention period, five practices (CMC, HJC, RH, SMC and WS) demonstrated slight decreases in overall NSAID prescribing ranging from 0.2% to 0.4%. Three practices showed no change in percentage of patients on NSAIDs. Four practices showed slight increased proportion of patients on NSAIDs of between 0.1-0.2%.

The results suggest no major increase or decrease in overall trend in NSAID prescribing in either group. However, trends are suggestive of a greater reduction in the intervention group with RH and WS practices having greater overall decreases than other practices. It is not feasible to demonstrate major shifts in numbers of patients prescribed NSAIDs from this data as proportion of patients on NSAIDs represent a relatively small proportion of each practice population.

5.4.2.2.2 Patients over 65

Proportion of patients over the age of 65 years on an NSAID ranged from 30.5% to 45.5% of patients in six of the seven benchmark practices. Only one practice (WL) had a relatively low proportion of elderly patients on an NSAID (14.4%), possibly because it was a city practice with a high young (student) population. During the intervention period, (with the possible exception of SY practice) there was no major change in patients over 65 years on NSAIDs in benchmark practices.

The proportion of patients on NSAIDs over the age of 65 in intervention practices at baseline ranged from 21.1% to an exceptional 72.2% in one practice. During the intervention period, only one practice (TS) demonstrated a moderate reduction in proportion of patients over 65 years on an NSAID.

There was no observable difference between intervention and benchmark for reduction in proportion of elderly patients on and NSAID.

5.4.2.2.3 Total (Clinical) Risk Factors

Total risk factor figure is a composite of gastrointestinal (peptic ulcer), renal insufficiency (as indicated by chronic kidney disease classification), cardiovascular and cerebrovascular risk. To an extent, reliability of this data relies on accuracy of the documented Read Code on the practice system. Where Read Codes were documented, this should alert the prescriber to any potential risk related to prescribing of NSAIDs.

Only three patients in the benchmark group (RMC) and one patient in the intervention group (WS) were coded for peptic ulcer, suggesting that there was awareness of NSAID-associated gastrointestinal risks and that NSAIDs were not generally being prescribed in this high-risk group. Of concern perhaps, is that three patients with documented PU were registered in one practice. All other data was based on documented cardiovascular and renovascular Read Codes.

The proportion of patients prescribed an NSAID with pre-intervention documented risk factors ranged from 4.1% (WL) to 22.4% (SY, high student population) in the benchmark group and 1.9% to 27.8% in the intervention group. In reality, actual numbers of patients with documented risk factors were generally small in both benchmark and control groups thus not enabling clear conclusions to be drawn from this data.

There are no major increases or decreases in proportions of patients with documented risk factors in intervention practices. Possible exceptions are PH, practice with a reduction of 6.1% and HJC with a total risk reduction (mainly renal) of 8.0% and are believed to reflect specific practice actions to address NSAID prescribing in patients with specific risk factors.

	Percentage of Patients								
	% Practice Population on NSAIDs			% Patients >65 on NSAIDS			% Patients with Risk Factor (CV, CR, GI)		
Practice	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**
BENCHMARK									
BW Surgery	2.6	2.8	0.2	34.5	32.1	-2.4	21.2	17.4	-3.8
CH Surgery	1.7	1.9	0.2	45.5	41.3	-4.2	16.3	15.9	-0.4
PF Surgery	2.6	2.6	0.0	30.5	33.3	2.8	13.9	12.7	-1.2
RH Centre	2.3	2.0	-0.3	27.4	27.8	0.4	14.0	15.2	1.2
SM Surgery	3.2	3.2	0.0	44.5	45.4	0.9	19.5	24.3	4.8
WL Surgery	1.4	1.6	0.2	14.4	7.8	-6.6	4.1	7.8	3.7
SY Surgery	1.9	1.9	0.0	43.1	35.4	-7.7	22.4	14.3	-8.1
INTERVENTION									
CM Centre	1.2	1.1	-0.1	25.0	29.3	4.3	1.9	2.0	0.1
CH Surgery	2.7	2.8	0.1	29.7	27.2	-2.5	15.0	16.7	1.7
DM Centre	3.2	3.2	0.0	51.4	51.7	0.4	8.8	8.3	-0.5
SE Centre	4.3	4.5	0.2	40.4	41.5	1.1	27.8	26.1	-1.7
SG Surgery	4.0	4.1	0.1	48.4	45.2	-3.2	8.7	11.1	2.4
HJ Centre	2.5	2.4	-0.1	34.6	42.3	7.7	25.0	17.0	-8.0
PH Surgery	2.4	2.6	0.2	21.1	21.7	0.6	21.1	15.0	-6.1
PF Surgery	3.2	3.2	0.0	34.7	37.5	2.8	11.4	13.4	2.0
RH Surgery	2.1	1.7	-0.4	42.5	42.2	-0.3	24.5	24.8	0.3
SM Centre	3.9	3.8	-0.1	37.4	42.3	4.9	25.0	25.9	0.9
TS Surgery	0.8	0.8	0.0	43.2	35.2	-8.0	12.6	11.0	-1.6
WS surgery	3.2	2.8	-0.4	72.2	70.9	-1.3	17.0	19.0	2.0

Table 5.32 Movement in Patient-Orientated Outcome Indicators from Baseline to Post Intervention

	Percentage of Patients								
	%PPI			% ASPIRIN			% SSRI		
Practice	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**	**Pre**	**Post**	**% Diff**
BENCHMARK									
BW Surgery	51.7	51.8	0.1	9.9	8.5	-1.4	14.3	13.8	-0.5
CH Surgery	38.8	39.3	0.5	10.1	7.5	-2.6	12.4	9.5	-2.9
PF Surgery	37.7	38.0	0.3	7.9	8.7	0.8	10.6	15.3	4.7
RH Centre	31.3	33.8	2.5	7.3	7.9	0.6	16.2	18.5	2.3
SM Surgery	43.0	49.4	6.4	12.5	15.0	2.5	10.0	12.0	2.0
WL Surgery	32.0	39.7	7.7	6.2	7.8	1.6	13.4	10.3	-3.1
SY Surgery	44.3	38.3	-6.0	17.8	13.1	-4.7	6.3	6.9	0.6
INTERVENTION									
CM Centre	45.2	44.4	-0.8	6.7	10.1	3.4	6.7	11.1	4.4
CH Surgery	32.7	37.7	5.0	9.8	9.5	-0.3	9.0	12.7	3.7
DM Centre	26.1	29.3	3.2	19.8	15.5	-4.3	3.6	6.0	2.4
SE Centre	31.0	33.0	2.0	18.1	15.4	-2.7	10.7	10.7	0.0
SG Surgery	50.0	46.0	-4.0	10.3	4.0	-6.3	8.7	9.5	0.8
HJ Centre	29.8	43.3	13.5	13.5	12.4	-1.1	8.7	12.9	4.2
PH Surgery	39.4	39.2	-0.2	11.0	9.2	-1.8	12.8	14.2	1.4
PF Surgery	46.9	53.8	6.9	14.0	12.8	-1.2	11.1	10.8	-0.3
RH Surgery	36.7	37.0	0.3	13.5	11.9	-1.6	5.5	5.9	0.4
SM Centre	48.0	51.6	3.6	21.0	22.9	1.9	18.0	19.9	1.9
TS Surgery	40.0	45.1	5.1	9.5	7.7	-1.8	5.3	4.4	-0.9
WS surgery	25.0	25.9	0.9	13.2	10.6	-2.6	22.6	21.2	-1.4

Table 5.33 Movement in Patient-Orientated Prescribing Outcome Indicators from Baseline to Post Intervention

5.4.2.2.4 Prescribing Indicators Concomitant Medication

Summarised in Table 5.33

Several drugs (aspirin and SSRIs) may increase bleeding risk in patients on NSAIDs. Co-prescription of PPIs, is recommended for gastroprotection in patients with a higher bleeding risk on NSAIDs.

There were no obvious trends to suggest an increased use of PPIs or decreased use of aspirin or SSRIs in patients prescribed NSAIDs in the benchmark group. Data from WL and SM practices may suggest a limited increase in the use of PPIs with a reduction in SY.

In the intervention group, there were moderate increases in the use of PPIs in seven of the twelve practices (CH, DMC, SE, HJC, PF, SMC and TS). There was also an indication of reduction in concomitant prescribing of aspirin in SG, SE, DMC and WS practices.

No obvious differences in prescribing of SSRIs were detected. In general, the differences in numbers may generally have been too small to detect any major shifts or to be able to draw any significant conclusions regarding prescribing of concomitant medications.

Chapter 6

Results Qualitative Evaluation

6.1 Introduction

This section summarises the qualitative study evaluation and is divided into two parts. Firstly, GP perceptions, attitudes and beliefs regarding EBM, (essentially collated from pre-intervention interviews), are summarised and discussed in the context of the GP curriculum requirements and with reference to the current literature on what is known on the subject. The second element focuses on post-intervention feedback from GPs on the impact of the intervention itself and whether and how it influenced the way GPs worked. It also considers the value GPs themselves placed on the intervention and whether it was beneficial as a working model. Table 6.1 provides a summary of GPs participating in pre-intervention and post-intervention interviews including practice base and identification code.

GP Interviewee	M / F	Years as GP	Practice	SP	PL	GP Trainer	Colour / Code
Pre-Intervention							
1	M	22	SGS	√			Pre 1 Quote
2 *	M	12 (22)	DMC	√	√		Pre 2* Quote
3 *	M	8	SMC		√		Pre 3* Quote
4	M	7 (12)	CHS		√		Pre 4 Quote
5	F	10	SEC				Pre 5 Quote
6	F	5	TSS				Pre 6 Quote
7	F	12	PFS				Pre 7 Quote
Post-Intervention							
1	F	25	PHS	√	√		Post 1 Quote
2	M	7	SEC		√		Post 2 Quote
3	M	12	PFS		√	√	Post 3 Quote
4 *	M	12 (22)	DMC	√	√		Post 4* Quote
5	M	15	WSS		√		Post 5 Quote
6	F	12 (30)	SMC			√ +	Post 6 Quote
7 *	M	8	SMC		√		Post 7* Quote
8	M	3	HJC				Post 8 Quote
9	F	11	PFS				Post 9 Quote
10	F	11	CMC		√		Post 10 Quote
11	F	24	TSS				Post 11 Quote
12	M	22 (31)	RHS	√	√		Post 12 Quote
13	M	12	SGS		√		Post 13 Quote

* Denotes GPs interviewed pre-intervention and post-intervention
() – Years Qualified
SP - Senior Partner
PL – Nominated GP Practice Prescribing Lead
+ - Medical School Teacher

Table 6.1 GP Interviewees Summary of Characteristics

6.2 GP Knowledge and Perceptions of EBM

6.2.1 GP Knowledge and Training

'Evidence-Based Practice' is a fundamental component of the RCGP Curriculum. The RCGP adopts the principles of the Sicily Statement (2005), and endorses the five-step model of EBP in teaching individuals how to formulate an answerable question and, to access, critically appraise, apply and evaluate the evidence in practice.[211,212]

Key RCGP Evidence-Based Practice learning outcomes are summarised in Table 6.2

GPs participating in pre-intervention interviews indicated that none had received specific training in Evidence-Based Medicine as a topic or as a 'discipline' during their medical training. However, several indicated that the local MRCGP course contained a formal component involving critical appraisal and evaluation of a clinical research paper. Consequently, most GPs appreciated the principles and importance of critical evaluation of clinical studies although several clearly regarded the training more a means to an end (passing the exam) than something they would routinely incorporate in practice.

The GPs concurred in that a considerable amount of decision-making in medicine is not necessarily evidence-based and that evidence to support rational decision-making is often lacking, creating a void in terms of informing best practice. GPs often relied instead on traditional and habitual practice in their decision-making.

- an awful lot of what we do particularly in primary care, but for medicine generally is not necessarily evidence based, an awful lot of interventions that nobody knows whether they really work, it is just we have always done them. (Pre-1)

Apparently, prescribing decisions were not necessarily based on sound knowledge either.

- I mean it's 'cookbook' medicine. I mean you look it up and think 'that looks alright, I'll have one of them'. (Post-1)

GPs described several influences on their routine prescribing including patient factors, personal prescribing habits, familiarity with particular drugs, because they 'had always done it that way' and a reluctance to move out of their perceived 'comfort zone'.

The GPs recognised that for evidence to bring about change in their practice, individuals needed to actively change and move from established habitual practice, to incorporating known evidence into decision-making. The personal process involved 'taking the message on board' (or internalising the relevant information).

- it's that habits are habits and to change habits you need to actually actively change otherwise you slip back into the habits, and evidence comes along and you start to make changes. (Pre-1)
- And actually it's quite difficult to change some of those things if you've always done it one way. (Pre-2)

The main inference, however, was that changing prescribing habits was not something GPs considered actively or willingly themselves.

Royal College of General Practitioners Curriculum

Statement 3.5 Evidence-Based Practice

'Evidence-based care as a discipline requires GPs to find the best evidence, subject it to critical appraisal, understand its relevance and application in specific circumstances and then to communicate this knowledge appropriately and effectively both to individual patients as well as the wider healthcare team.'

Core evidence-based practice competencies
All GPs should be able to:

- Ask the 'right questions', to enable an efficient search to:
    - Find the appropriate literature from the widest available sources
    - Apply rigour in appraising the literature
    - Place the answers in the appropriate context
    - Demonstrate relevant skills so as to instigate change in practice effectively
    - Show an ability to design and initiate appropriate evaluation

Primary Care Management
GPs should be able to:

- Demonstrate that they base their treatment and referral decisions on best available evidence
- Apply rigour to scientific research to decide whether evidence is applicable to the primary care setting and appropriate to the individual
- Demonstrate sufficient knowledge of the breadth of scientific evidence in order to provide best information for the individual
- Use their knowledge of the 'best possible evidence' to inform a patient of the 'best possible' way to navigate the healthcare system.

A Comprehensive Approach
The GP should have the ability to:

- Demonstrate an understanding of what the limitations of evidence are in patients with chronic disease or the very elderly (often excluded from trials) in primary care.
- Demonstrate an understanding that trials looking at therapeutic interventions may come from studies that exclude patients with significant co-morbidity

Scientific Aspects
The GP should have the ability to:

- Demonstrate that evidence needs to be gathered from the most appropriate, rather than the most readily available source. GPs should be able to determine whether the evidence presented to them is sufficient and rigorous enough to be analysed in the context of a patient.

Table 6.2 RCGP Curriculum Requirements - Evidence-Based Practice

6.2.2 Definition of Evidence Based Practice

Overall, the GPs believed that clinical decision-making should be objective and informed by the best and strongest available research evidence. However, they found Evidence-Based Medicine a difficult and complex concept to define.

- Oh that's difficult isn't it? (Pre-3)
- I think its probably fairly difficult. (Pre-6)

None of the GPs proffered the 'recognised' Sackett definition (Section 2.2) or suggested that EBM involved the traditional 'Five-Step model 'for finding answers to clinical questions as the basis for clinical decision-making. Rather, their understanding of EBM focused on the principle of incorporation of best research evidence from clinical trials into clinical decision-making for individual patients.

One definition representing the general view was:

- I suppose looking at the whatever the best evidence is, or making a rational decision and then, I still think the key, which is what we probably do best as GPs is trying to, make the best fit of our patient to, say a different patient group. (Pre-2)

6.2.3 What Constitutes the Evidence Base

Generally, GPs considered that the 'evidence base' for prescribing largely results from studies or clinical trials, conducted in clearly defined populations for the purposes of research. Results from clinical trials were considered not normally generalisable to the general population as seen by GPs because studies are typically conducted in highly selected groups of individuals, generally excluding those with a more complicated clinical picture.

- Well I treat 100% of patients, so I don't exclude people with IHD or people with diabetes or people who have had a stroke or people who are obese or people who smoke. I treat all of those and therefore I am sceptical that the evidence that they say, you should do this from a single trial doesn't necessarily apply to the patients that I'm treating. (Pre-2)

The elderly population in particular was regarded by several GPs as being quite different from the general population where recommended treatments were often clinically inappropriate for individual elderly patients.

GPs were therefore generally aware of limitations associated with research evidence obtained from clinical trials as highlighted in the RCGP curriculum. Several also regarded studies providing patient-orientated outcomes-based evidence (e.g. UKPDS) as more relevant than those with narrow disease-orientated outcomes. Others realised that conclusions drawn from robust evaluation of several studies by reputable groups (e.g. Cochrane) contributed to the evidence-base, making it stronger.

Despite availability of evidence-based recommendations, individual patient factors were regarded as a key influence in determining the most appropriate therapies. GPs also felt that they often have a wider picture and hence, a more holistic approach to patient management. Tension between EBM and the perception of medicine as an art, was also implied, there being no substitute for experience, tacit knowledge or even 'sixth sense' when making decisions or diagnoses regarding particular patients.

The GPs were therefore familiar with two accepted criticisms associated with EBM, that is, the reductionist nature of evidence derived from clinical studies and the need to acknowledge patient values and subjective experience, as well as physicians 'tacit' knowledge in clinical decision-making.[213]

6.2.3.1 Evidence Based Medicine as an Event

GPs observed that availability of evidence to inform practice was continually evolving and changing. The whole process was perceived as dynamic and not permanent.

Two concepts of evidence influencing clinical practice emerged from the interviews. One was described as 'evidence-based', resulting from well researched and well documented studies and tied in with GP views on what constitutes 'the evidence base'. The other, more nebulous, possibly unwritten, founded on traditional or long-standing practice, was described as 'practice-based'.

- I guess the other side of it is a bit more woolly side of it, the things that have been done for a long time, so, aspirin and the kind of things that don't necessarily have written evidence-base but have that practice-base. (Pre-5)

It was suggested that, as information accumulates, evidence often 'comes about' ultimately resulting in changes in practice, a notion which perhaps conforms to the GP 'practice-based' concept of evidence influencing practice but which mainly fits the 'passive diffusion' model of evidence transition.[36,214]

6.2.3.2 Benefits of Evidence Based Medicine

The evolution of EBM overall was generally perceived as supporting a less nebulous approach in medicine by providing firmer evidence on which to base clinical decisions. Consequently, benefits of EBM were regarded as cleansing of inappropriate historical practice, removal of nebulous practice and better standardisation of care.

6.2.3.3 Motivations for Practicing EBM

All of the GPs interviewed considered themselves as evidence-based practitioners. Their motivations for practicing EBM included keeping up-to-date with best-practice recommendations, to inform and justify clinical decision-making, and where necessary, to ensure value for money. GPs were conscious that there is a potential for doctors, to do more harm than good. Therefore, principles of beneficence and non-malfeasance were also motivating factors in practicing evidence-based medicine.

6.2.4 GP Skills and Information Management

GPs felt that they were inundated with large volumes of information and believed that it was impossible to keep up to date with everything as they did not have time to read or access it all.

- you know there are so.., there are too many resources actually. (Pre-3)

The complexity of freely available information, often from conflicting sources, and difficulties encountered in dissecting all the contributing factors were difficult for GPs to assess.

- This is the problem you see, it is so difficult to unpick. (Pre-3)

It was felt that a 'humble' GP has no means of judging how robust evidence is as presented to them in articles or journals and that much of what they read, they may take on trust.

All of the interviewees believed that the average GP has neither the knowledge nor the skills to perform a literature search, or to review and evaluate the evidence-base themselves. Accessing and evaluating research evidence was regarded as a highly skilled job, reserved for individuals with appropriate skills.

- It takes time and it takes skill. And I'm sure somebody else could do that. I mean I can't. Erm and that's, that's *(laughs)* it's your job. (Pre-6)

Despite general enthusiasm for EBM, GP feedback supported other findings in that physicians rarely report using evidence-based guidelines or studies identified from a focussed literature search to guide their clinical decisions, and that most GPs are not confident in even the basic skills of EBM including literature searching and critical appraisal.[215,216]

The feedback also suggests that most GPs are actually unable to demonstrate the required *'Core evidence-based practice competencies'* as defined in the RCGP Curriculum and are consequently unable to apply those competencies in practice.

GPs believed that even if they had relevant skills, they did not have time to search for information themselves, generally 'picking up' information as they went along, and only actively seeking information if they had to. GPs preferred information aimed at them to constitute the 'bottom-line' with key messages and salient points, preferably condensed on one A4 sheet.

- Even things like the NICE Guidance, I only ever read the kind of you know, summaries, because my brain can't take in all the other stuff you know. Just put it down to one side of A4. (Pre-1)

6.2.4.1 Keeping Up to Date

Lack of awareness of available evidence was regarded as a barrier to incorporation of evidence into practice. Unless GPs were made aware of evidence, their knowledge of emergent evidence ultimately depended on serendipity.

- My barriers would be not knowing about it. My ignorance or lack of awareness of things. (Pre-4)

Only two interviewees indicated that they specifically attempted to keep up to date with the most recent evidence-base by attending regular (RCGP accredited) 'GP Update' courses which addressed 'current issues, in general practice'. Both utilised and relied significantly on pre-appraised information collated by GP trainers as part of the course.

- a bunch of GPs have read through all the articles and all the journals and put all the current evidence based management of everything and anything into a book.(Pre-4)
- What we would effectively do is to keep up to date, pre-digested evidence-based guidelines. (Pre-6)

Several GPs accessed Web-based tutorials of their choosing. Others attended consultant-led 'hot topics' courses co-ordinated by the local Trust post-graduate medical centre. Most did however not indicate that they actively sought up-to-date evidence-based information to inform their practice.

6.2.4.2 Background Reading

The British Medical Journal (BMJ) was considered gold standard and read regularly by most GPs. Several read other GP 'magazines' distributed opportunistically.

- The ones I get sent. *(laughs)* GP magazines often have a round of the latest sort of studies and things, which is quite helpful. (Pre-5)

Several GPs were clearly aware of the potential for manipulation of information presented to them in any source of information. Some were sceptical of information presented to them, particularly where product advertising was included. Others did not apparently discriminate or question the quality or validity of the evidence-base in their reading materials.

6.2.4.3 GP Colleagues

The interviews confirmed that an informal network of verbal communication existed between GPs in seeking information from each other to inform their clinical decision-making. They frequently asked specific questions of their GP colleagues, usually when they met informally during the working day (e.g. break times) or during regular informal meetings.

- We, meet, every morning and have sort of informal discussions about patients, and that came up as very informal. (Pre-5)

Several practices organised educational and clinical meetings with the stated intention of information-sharing and 'book-club' type discussion and which were also regarded as an opportunity for GPs to share current issues in practice with each other.

6.2.4.4 Consultant Specialists

GPs also contacted consultants when they had clinical queries regarding the management of individual patients. They observed however that consultant opinions frequently conflicted with each other.

Overall, feedback indicated that in line with other studies, GPs preferred to rely on clinical experience, opinion of colleagues and brief reading as a means of information-gathering to inform their clinical practice, which ultimately would serve to reinforce their reliance on 'mindlines' in influencing individual clinical decision-making.[4,40,41]

6.2.4.5 Medicines Management Team

Several GPs utilised MMT for obtaining prescribing advice, particularly relating to prescribing policy. Consultant requests often prompted GPs to seek further advice to inform prescribing decisions. Responses were generally considered evidence-based although cost-effectiveness was assumed to have been a major consideration.

- presumably you lot have all looked at the drugs, decided what the evidence base behind, how much they all cost….(Pre-6)

Depending on the query, community pharmacists, hospital pharmacists and hospital doctors were often contacted in preference to MMT. Several GPs were unaware of the skill-base within MMT or of the prescribing advice it could provide.

- I didn't really know we could do that. And we've probably been using much less skilled people than you. We'll often be phoning up sort of registrars in hospital and probably you lot are a lot better to talk to than nurses. (Pre-6)

This observation should perhaps raise questions if not concerns regarding GP perceptions of the role and functions of MMT. It suggests that MMT may not have been successful, active (or even interested) in communicating itself as a medicines resource available to support GPs in practice.

6.2.4.6 Guidelines in Practice

GPs generally accessed clinical guidelines to inform practice. However, they preferred summaries only and were unlikely to access and read full guidance documents. Guidelines were regarded predominantly as working models to guide practice in line with clinical knowledge and expertise, rather than an instruction to be followed slavishly. Although constantly changing, guidelines were considered to be the best influence available at any one time to inform decision-making.

Most, if not all GPs used NICE Guidance to inform their clinical practice. NICE and (its Scottish equivalent) SIGN guidance (Scottish Intercollegiate Guideline Network) were regarded as gold standard evidence-based guidelines. SIGN, was considered to be the more evidence-based by those GPs who used it. Frustration was also expressed that NICE and SIGN were often inconsistent.

Several GPs were sceptical about the 'evidence-base' on which NICE had based several therapeutic recommendations in its guidance (e.g. neuropathic pain).

Some GPs were cynical about the NICE cost-effectiveness stance, sometimes perceived as a rationing exercise whilst on others, recommending expensive drugs without supporting evidence. NICE Guidance was also often open to interpretation, which generated uncertainty, ultimately making it more difficult to implement.

Several GPs suggested that some clinicians agree with and trust NICE guidance unquestioningly whilst others (including several interviewees) were more sceptical. Several GP comments are summarised in Table 6.3.

Guidelines in Practice	
GP Scepticism	• So, You have to question why the national organisation like NICE actually permitted itself to write a national guideline not based on any evidence at all. And I think that is something that they have got to be very, very wary of, it devalues a lot of the good things that they have done because it is so patently wrong. (Pre-4) • So yes, I think it is to be taken with a grain of salt. Often excessively (Pre-6)
GP Frustration	• I do believe in NICE guidelines, I do believe in SIGN guidelines and sometimes despair that the two don't necessarily agree with each other because they should reflect each other exactly. (Pre-4) • Yes, lots of different ways of interpreting actually what should be a very straightforward guideline. (Pre-3)

Table 6.3 Summary of GP Comments on Guidelines in Practice

British Society Guidelines such as the British Thoracic Society (BTS), British Heart Foundation (BHF) and The British Hypertension Society (BHS) were regarded by several GPs as evidence-based sources, which they accessed to inform specialist areas of practice. However, GPs who used these sites did not acknowledge that these sources were not independent and may not have been evidence-based or unbiased.

6.2.4.7 Triggers for Seeking Information

Various triggers may have prompted GPs actively to seek information. Typically, where 'evidence-based' guidelines were poor or not relevant to practice and when GPs were pursuing personal professional development. The main and most frequent trigger, for GPs in seeking information however, were patients, typically the 'informed patient'. Seeking and accessing information was often conducted during patient consultations and usually via the internet.

6.2.5 The Internet

The Internet (regarded as a 'wonderful', and incredibly powerful tool) was the main means by which GPs accessed information. Several GPs acknowledged that there is little control in terms of access and no guarantee of the credibility or validity of information available from it. Overall, GPs determined individually which websites to access although in one practice, GPs shared information on internet sites amongst themselves.

- on our Monday educational meeting we have a regular slot on the internet where we just discuss what people are using because it's just so powerful and it's so important now. You can't ignore. (Pre-3)

GPs routinely worked throughout the day with numerous preferred websites open and ready to use. Accessing information via the internet was an integral and routine part of patient consultations. Many GPs during their interview demonstrated (unprompted) how they would use the internet.

- I do it all day, every day. It's constant. Yep. I do it with the patient there. (Pre-3)

6.2.5.1 Frequently Used Websites

Websites were frequently used by GPs to access information and to guide patients to further information. One GP even directed patients to physiotherapy exercises on YouTube.

- They feel empowered because actually they can use the internet in a way which is focussed by someone for them rather than just trying to fish. (Pre-3)

GP Notebook (independently managed, online encyclopaedia of medicine for GPs) was routinely accessed by many GPs to inform their practice. It was perceived as a 'well researched and validated' information site. Patient.co.uk, aimed at non-medical individuals (EMIS funded), was frequently accessed during consultations with patients, often used for directing patients to further information and for accessing patient information leaflets issued during consultations.

- It's a good sort of one stop thing. (Pre-1)

Neither website was acknowledged as commercially funded, or that the information posted had not necessarily been validated or subject to evaluation through a recognised critical appraisal process.

GPs mainly accessed British websites, particularly when seeking guidelines, clinical advice and patient-orientated information. Foreign websites were accessed more for clinical knowledge-based information than for evidence to inform decision-making.

If GPs had specific information requirements unavailable through routinely used links, Google was undoubtedly the first and main route to actively seek and access further information.

- Well you Google things for finding them don't you? It's where you find everything these days. (Pre-4)
- Oh crikey. I could look one (definition of EBM) up for you on Google if you like. That's what I would normally do. (Pre-3)

Use of the internet as a tool during GP consultations has apparently coincided with the internet revolution and expansion. In this situation, GPs are relatively time limited. However, they appear to be using the internet to obtain quick answers to questions or as a means to provide patient support. Although patients often come with information obtained from the internet, (a source of frustration for many GPs) GPs were conversely using the technology to manage patient queries during consultations.

6.2.6 Trusting Information

A major theme emerging from the interviews related to trust. Trust in the evidence itself, trust in 'evidence-based' guidance, and trust in the original studies. Trust was also a factor mentioned in relation to other sources of information including the pharmaceutical industry, internet websites and the Medicines Management Team.

There was a disparity amongst GPs regarding their questioning the validity of evidence-based sources (including NICE), some GPs were clearly more questioning than others. Several GPs assumed, (based on trust), that guidelines, websites aimed at GPs and patients and other resources were reliable sources of evidence-based information.

Other GPs were more cynical and appreciated that information may be distorted in the way it is presented to them. Understanding motivations behind 'evidence' as presented for example by drug companies compared with NICE was regarded as important in discriminating between what may or may not be evidence-based information.

6.2.7 Evidence Based Sources of Information

Cochrane, Clinical Evidence, NICE, SIGN, Clinical Knowledge Summaries (CKS) and the NPC are all organisations with robust and transparent methodologies for the production of high quality evidence summaries.[217]

CKS (formerly Prodigy) is an accredited 'NHS Evidence' based service provided by NICE which provides GPs with a readily accessible summary of the current evidence base and practical guidance on best practice for common and significant primary care presentations. Several GPs used it as a source of information to inform clinical practice, including prescribing, however, others were completely unaware of its existence. Most used GP Notebook instead.

A limited number of GPs did discriminate between information sources which were regarded as providing reliable evidence-based summaries, such as the Drug and Therapeutics Bulletin (DTB), Bandolier, MeReC, and Cochrane. Several GPs also exercised discretion in preferentially accessing NHS or DH websites, whereas others did not.

The majority of GPs however, did not preferentially access recognised evidence-based sources of information routinely, possibly because many GPs have not been educated in accessing reliable sources as a component of information management.

A selection of interviewee comments on discriminating between and trusting available information-based resources are summarised in Table 6.4.

Information Sources	
Trusting Information	• my assumption is that its (NICE) always evidence based and I haven't thought any more about it. (Pre-4) • I think with the sites that I know, is that I trust them and perhaps I shouldn't, *(laughs)* But you know, I have never really thought about it to be honest. (Pre-5) • I'm a great questioner. But I think a lot of GPs aren't. Mainly really because they haven't got the time. I guess I'm very passionate about what I do so, I always… I love to know (Pre-7) • I suppose for things like GP notebook, you just have to take a leap of faith don't you? You just, you know you have to trust your peers to some extent. (Pre-6) • I think I would, describe myself as an eternal sceptic when it comes to a lot of things which are said about the evidence and what it actually means (Pre-2)
Evidence-based sources of information	• I would, trust Bandolier DTB and NICE because I don't think these people have got axes to grind one way or another, they just want to give the best advice and they are independently funded. (Pre-1) • ...have been, appraised by Cochrane or NICE or, the MHRA. There is always a conclusion by reference to one of those big bodies, who have appraised those studies and the articles. (Pre-4) • because you know, a website that's dot nhs dot uk or dot gov dot uk is hopefully going to be more evidence, more sound, than you know, some website *(laughs)* in the States. (Pre-1)
Accessing relevant information	• Nobody sits you down and says, you know, these are the most effective sources of information to use, everyone is groping around trying to find sort of relevant sources of information. (Pre-6)

Table 6.4 Summary of GP Comments on Information Sources

6.3 Discussion

6.3.1 GP Perceptions of EBM

There was widespread acceptance of the concept of EBM. However, there remains a diversity of approach to EBM in clinical practice involving different interpretations and understanding. Since the introduction of EBM as new paradigm for practice and teaching in medicine, various conceptual models have evolved. Initially focussing on using research evidence as a basis for clinical decision-making, later models incorporated components such as patient values, clinical expertise, clinical state and setting.[218]

Critics argue however, that EBM is not well developed and articulated in terms of defining model components, justifying their inclusion or suggesting ways to integrate them in clinical practice.[218] Essentially, although EBM is a desirable aim, the 'how to' practice it is not specified.[218]

Even early proponents of EBM no longer believe that it represents a new or special theory of knowledge. They acknowledge that there exists an inadequate framework for successful problem-solving and decision-making and concede that there remains a lack of evidence that EBM improves patient outcomes.[213] They suggest that rather than being construed as a scientific or philosophical theory that changes the nature of medicine, that EBM should be considered as a continuously evolving heuristic structure for optimising clinical practice.[213]

In the clinical context, EBM may therefore be regarded as having two different but related meanings. Firstly, as a method to access and evaluate research evidence on clinical effectiveness of treatments, which requires highly developed skills in accessing evidence to answer clinical questions and secondly, as a model of practice in the clinical encounter, equated with 'best practice' in clinical decision-making.[218]

Another perhaps related classification has also been suggested whereby EBM may be regarded as being applied to improve healthcare at two different levels.[219,220] Evidence-Based Healthcare (EBHC) practiced at an organisational level focuses on population-based policies and individual decisions, which are consistent with evidence of effectiveness and benefits. In this model, evidence-based research findings are embedded into national systems and processes through the use of guidelines and audit.[219,221] Evidence-based guidance (EBG) is produced by teams using rigorous methods to produce generic guidelines and policies that address needs of groups of people. (e.g. Cochrane, Clinical Evidence).[219] This model also fits the 'Implementation' approach to spreading research findings in practice or 'making it happen' by mainstreaming innovation within an organisation.[214] (Section 7.3.4)

Evidence-based Individual Decision-Making (EBID) however, is the practice of EBM by individual clinicians making decisions about individual patients and their care. EBID involves filtering and interpretation of information coming from EBG within clinical decision-making.[219] In this model EBID also focuses on incorporation of evidence or 'best practice' in clinical decision-making for individual patients.

Despite stated aspirations to practice as evidence-based practitioners, the GP interviewees found EBM a very difficult and complex concept to define and were unable to offer a clear and agreed definition of what constitutes EBM.

In many people's minds, EBM is about formulating questions, literature search and critical appraisal or the traditional five-step approach to EBP.[222] The RCGP Curriculum also requires that GPs should be able to demonstrate these competencies. This was not however the participants' perception of practicing EBM or an activity which any would normally apply in their clinical practice.

Rather, application of EBM in practice as described by the GPs focussed on the principle of incorporation of best research evidence into clinical decision-making for individual patients, or, applying it as a model of practice in the clinical encounter, equated with 'best practice' in clinical decision-making.[218] This perception is also congruent with the EBID approach described by Eddy and others.[219,221]

Feedback suggests that whichever classification of EBM is inferred, GP understanding and application of EBM in practice fits in with the use of 'best available evidence' to inform decision-making at the individual patient level.

Interestingly, GPs perception, that changes in practice often occur as a result of an accumulation of evidence which happens over time, conforms with the 'passive diffusion' model of evidence transition.[36,214] However, the EBID approach, (informed by EBG) is consistent with 'implementation' at an organisational or policy level.[36,214,219]

6.3.2 Skills and Knowledge

Despite positive attitudes towards EBM, GPs indicated that they simply did not have the basic (traditional) skills to practice EBM. GPs seeking evidence-based answers to clinical questions was not an option for them. Rather, it was someone else's responsibility or role. As reported earlier, GPs relied mainly on clinical experience, opinion of colleagues and brief reading to inform their decision-making.[215,216]

Information gathering in this way is consequently likely to reinforce GP reliance on 'mindlines' to support their clinical decision-making.[4,40,41] Most information doctors use when seeing patients is therefore kept in their heads, which may be appropriate if the 'mindlines' reflect best evidence but not if they serve to reinforce outdated and sub-optimal practices.[223] Unfortunately, much of that information is out of date and wrong and studies evaluating markers of clinician knowledge have demonstrated severe deficiencies in doctors' knowledge.[216]

The GPs in this study also found the volume and complexity of information around them overwhelming and without appropriate skills were unable to evaluate or judge the quality of 'evidence' presented to them, taking much of what they read on trust. Most GPs did not search for information themselves, generally 'picking up' information as they went along, only actively seeking information when they had to.

Unfortunately, information management is not generally taught to medical students as a critical professional skill.[216,222,224] Paradoxically the EBM movement has concentrated much resource on teaching the more difficult traditional 'Five-Step model approach for finding answers to clinical questions as the basis for clinical decision-making, and which evidence from this study suggests is not applied in practice.[216,222]

The EBM movement has attempted to make it easier for clinicians to access evidence-based information to inform clinical decision-making.[217] Despite high quality syntheses of evidence, and despite continued efforts, research evidence still does not translate into practice.[225,226] In many therapeutic areas, existing prescribing data is different from anticipated prescribing patterns if prescribing decisions were based on available evidence.[223]

Cardiovascular risk associated with NSAIDs use is just one example. The statistically significant differences achieved in influencing prescribing of NSAIDs in this study, also suggests that there remains a wider problem to be addressed in raising awareness of research findings with GPs and then persuading them to adopt a change in prescribing behaviour.

Adoption of evidence into practice ultimately depends on decisions to change made by individual people.[224] The GPs recognised that to bring about change in prescribing practice, individuals needed to actively change and move from established habitual practice, to incorporating known evidence into decision-making. There was however, reluctance for GPs to move from their 'comfort zone' and instigate change in personal prescribing habits themselves.

In an environment of information overload, questions therefore arise as to whether practitioners recognise when they do not have the best evidence for clinical decision-making. Too often practitioners don't know what they don't know and are unaware of important advances.[216] In this study, very few GPs acknowledged their own knowledge gaps because they were unaware of current advances or evidence-based recommendations.

GPs need to be aware how information reaching them can be flawed.[211,223] However, this review demonstrates that although several GPs discriminated between sources from which they accessed information, others took information that they sought or received on trust, frequently unquestioningly.

The RCGP Curriculum is quite clear in its requirements that GPs should be able to find and critically appraise the best evidence and understand its relevance and application in clinical practice. (Table 6.2) Whilst GPs were aware of limitations of evidence obtained from clinical trials, they were not apparently conversant with even the basic competencies of the traditional approach to EBM.

Based on the findings of this study, although many GPs are aware of the concept of EBM, perhaps worryingly, the majority do not actively seek, find or evaluate the best evidence with which to inform their clinical decision-making. Critical appraisal is not a skill routinely applied in practice by the majority of GPs. Many prescribing decisions were not based on the most recent evidence, or even on sound knowledge.

The RCGP Curriculum requires that GPs demonstrate that evidence is gathered from the most appropriate, rather than the most readily available source. Results from this review indicate that GPs actually adopt the opposite approach.

Study findings suggest that most of GPs activities in seeking information involve finding rapid answers to questions. Significantly, in the age of modern technology, when finding answers to questions (including during patient consultations), GPs often rely on rapid access to information available from the internet. Although GPs have preferred websites and several GPs are discriminatory in the sources from

which they seek information, many rely on information sought and received opportunistically and base their personal evaluation on trust.

It is suggested here that the 'Evidence-Based Practice' skills and competencies as outlined in RCGP curriculum aimed at ensuring evidence-based decision-making in every day practice are not routinely demonstrated or applied by the majority of GPs. It is of concern that GPs do not necessarily use evidence or up to date knowledge in their decision-making. GPs are not apparently equipped with certain traditional skills promoted by the EBM movement. Neither, are they trained in information management skills, which are aimed at managing information overload.

The GPs recognised that they do not have the time or the skills to access the evidence to inform their clinical decision-making. Instead, as suggested elsewhere, they tend to rely on unstructured reading, professional networks and advice of experts for information.[223]

Despite efforts to improve availability of synthesised evidence-based information, to inform clinical decision-making, many GPs still do not utilise information summaries which may never even reach them. GPs remain largely inactive, not actively seeking information unless prompted by a trigger into action, continuing to rely instead, on 'mindlines' as the basis for much decision-making.[225]

6.3.3 Potential Barriers to Implementation of EBM

Several factors were identified which may constitute barriers to implementation of EBM in practice. There was clearly reluctance on the part of many GPs actively to change and move out of their comfort-zone in relation to prescribing. Many were overwhelmed by amount of information available to them and were not able to manage it effectively because they lacked both traditional skills in EBM and information management skills. GPs remained recipients of information rather than seeking out the best information to inform their prescribing decisions.

A major factor was GP reliance on trust in the information they received or accessed opportunistically. Whilst several discriminated between the sources they accessed (using trusted websites and sources of information) and were sceptical of the evidence, others were apparently unquestioning about the credibility of the information reaching them. Many were unaware of validated information sources which also raises a question about how aware GPs are that the information they receive may be flawed. Lack of awareness of the evidence-base (blind spots) was also barrier to implementation of EBM.

Several aspects of this review are explored further in the discussion section of Chapter 7 in conjunction with other study findings.

6.4 Post-Intervention GP Interviews and Analysis

6.4.1 Traditional Interactions with Medicines Management Team

The intervention approach was regarded by GPs interviewees as being very different from traditional interactions with MMT about which they expressed several frank views.

Prior to the intervention, GP exposure to MMT, ranged from no personal contact to regular interaction with MMT staff. GP Prescribing Leads generally had greater contact because of their lead role responsibilities. Most GPs found the MMT Bulletin disseminated periodically to practices useful in raising awareness of general prescribing issues.

Annual Prescribing Meetings (APMs) typically involving a 'senior' MMT pharmacist meeting one-to-one with the nominated practice GP Prescribing Lead was the only direct contact several practices had with MMT. The meeting tone was generally considered dictatorial, with MMT telling the practice where they should concentrate efforts to achieve financial balance and make savings.

6.4.1.1 Prescribing Objectives

GPs expressed frustration regarding the many prescribing schemes 'imposed' on practices by MMT and the work and time demands that it generated for them. They felt inundated with prescribing data, reflecting at least five different prescribing schemes, all ultimately targeting cost-reduction.

'Point-in-time' listings of various prescribing indicators for all practices were disseminated regularly to each prescribing lead. Data was untargeted and did not provide feedback on prescribing trends. The volume and complexity of the information were considered overwhelming. Guidance on data interpretation and management to address MMT prescribing objectives was not provided. There was no personal contact as all communications were electronic.

Prescribing leads were expected to communicate relevant information to their partners, develop practice audits and to feed information back to MMT. GPs perceived little value in what they were being asked to do, believing it demonstrated completion of a task rather than providing useful information on practice prescribing activities. GPs believed that cold dissemination of large volumes of prescribing data did not persuade or help them to change prescribing behaviour.

6.4.1.2 MMT Culture

The overriding GP perception of MMT was that its raison d'être was based on minimising, if not reducing prescribing costs. GPs frequently felt pressurised to make prescribing decisions which were cost-based. The MMT approach to influencing prescribing behaviour was regarded as prescriptive, and restricting clinical freedom to prescribe. Existing tensions between MMT and GPs were implicit. MMT was also perceived as being inconsistent in promoting evidence-based arguments manipulating evidence to support its argument when the underpinning motive was likely to be based on cost. A selection of interviewee comments on traditional interactions with MMT are summarised in Table 6.5.

Traditional Interactions with MMT - GP Comments	
APMs	• The meetings are, basically, 'We're telling you, you've got to do this, you've got to change your budget'. (Post-1) • Well, I think when Medicines Management come, it's often adversarial. (Post-1)
MMT Culture	• Yes, within the Medicines Management, they are kind of focused to cost. (Post-8) • If we look at the quality prescribing programme, 'quality' in inverted commas, it's not really about quality, it's about efficiency, you know. We have to be a bit more honest about it (Post-7) • Well actually I've never met with people from Medicines Management, it's usually all done by e-mail and you're just being told what to prescribe (Post-6) • Sometimes I've felt a little bit let down when I've looked into it a bit more myself to feel that it's not entirely unbiased. That the cost side of things comes to influence what the final decision is. You get the evidence that supports the MMT argument but if there is evidence that is contrary to that it doesn't always get put forward. (Post-3)
MMT Recommendations	• And you think 'for goodness sake, you know, please be consistent with evidence-base because if you're telling us there's no evidence and then suddenly we're going to make a switch across to it, because suddenly the evidence is there, you suddenly become *incredibly* cynical. (Post-7) • It does feel like it's all about decreased cost. So I'm feeling a bit bruised about having swapped everyone to candesartan and now I've got to swap people back to losartan. I'm looking at these people who are looking at me as if I'm mad. (Post-11)
MMT Data and Prescribing Objectives	• There are four different areas that Medicines Management decides we have to do, which is ridiculous. Plus this, it's five different sticks you feel like you're being beaten with and you think 'Oh **** I should just go home'. (Post-7) • Sometimes there's so much to attack that you just think well where do I start with this, it's one list after another and it's a bit overwhelming. And it's a bit demoralising… (Post-11) • You know, my brain is not big enough to hold it all in, and I'm not stupid. It's a complete overload. I'll just keep seeing the patients. (Post-1) • But then once you get to a year, they just cut off the end, so you can't see a trend. You know, I want to see this three or four years ago (Post-7) • I would love to have the data set to see how we've changed over the years (Post-6) • it's the 'how do we go about sorting this out?' really. (Post-1) • You know it's all very much just get on and do it and we'll let you know once a year which I think you need a bit more feedback than that (Post-5) • I know this Medicine Management dashboard comes through to us, but even that, it's not giving you all the, all the data that you kind of need um, to work out what your, where you should be changing. • I mean I just feel as though that's almost like being marked. I don't know what that means. (Post-3) • We're supposed to have produced plans. We'll produce a report. But this isn't going to be a proper reflection, this is going to be tick-box stuff, isn't it? (Post-1)

Table 6.5 Summary of GP Comments on Interactions with MMT

6.4.2 Impact of the Intervention

6.4.2.1 On Prescribing Behaviour

Virtually all GPs interviewed expressed their belief that the intervention had influenced their personal prescribing behaviour (and that of their colleagues).

All believed that overall prescribing practice had changed within their practices as a result of the intervention. Most were aware that prescribing changes had been demonstrated during the intervention, the main impact being on prescribing of NSAIDs. External influences on prescribing in diabetes care were believed to have tempered the impact in T2DM although several GPs were aware of changes resulting from agreed actions within their practices.

Interviewee comments on impact on prescribing are summarised in Table 6.6

Impact on Prescribing Practice - GP Comments	
Practice Prescribing	• Oh, absolutely, because like I said, you know, we're now using um, naprosyn and ibuprofen and metformin a lot more. (Post 6) • ...had shown that our prescribing had actually er, had improved...(Post-3) • I can only imagine it probably improved a bit, even if it was just tidying round the edges (Post-11) • I do think probably our prescribing in diclofenac has *significantly* dropped... (Post-9) • Yeah I think it showed it (diclofenac) was going down. (Post-5) • And I think that has made a difference actually, especially to anti-inflammatory prescribing (Post-7) • It changed, I think overall it was very successful (Post 8) • Yes, prescribing Ibuprofen, Naproxen quite a lot. And gels. We prescribe a lot of gels (Post 2) • But really just I think what the best thing, we reduced the prescribing of non-steroidals... (Post 10) • Though I mean, you know, we've very definitely changed our practice. (Pre-7)
Individual GP Prescribing	• I never started people on Metformin like I do now. (Post 6) • I've changed some of my prescribing, you know, um, based on that feedback (Post 8) • Um, personally I prescribe less diclofenac. (Post 9) • I did certainly tighten up on the anti-inflammatories (Post-4)
Pharmacist Influence	• I don't think we'd have had any of the discussions we had around prescribing had we not been prompted by the pharmacist. (Post 4) • Having her expertise definitely I think helped with my individual prescribing decisions. (Post 3)

Table 6.6 Summary of GP Comments on Impact of Intervention on Prescribing

The GPs believed that through the intervention, pharmacists had influenced their prescribing habits in a way, which traditional communications with MMT pharmacists would not have achieved.

6.4.2.2 GP Knowledge and Behaviour

During interviews GPs recognised and reported that they had very limited pharmacology or therapeutics knowledge, topics which were apparently not included as key components of the medical training syllabus, the focus being on diagnostics. The intervention highlighted GPs lack of knowledge and understanding about medicines, (particularly new chemical entities with novel mechanisms of action) and the pharmacological basis of many interactions. Without basic pharmacology knowledge, the GPs were often unable to assess the clinical implications of prescribing new drugs in practice themselves. Many GPs believed that, their basic knowledge and education about drugs had increased because of the intervention, essentially filling a void in their knowledge.

Most GPs believed that their knowledge and awareness of the evidence base had increased because of the intervention, and that their underlying knowledge and understanding of the rationale underpinning prescribing decision-making had improved. The emphasis on promotion of research evidence was apparent throughout the visits. GPs were confident that the evidence presented to them was robust and they believed that they were prescribing in a more evidence-based manner because of the intervention.

6.4.2.3 Raised Awareness, Safety and Efficacy

In addition to increased awareness of safety and efficacy issues, there also arose greater GP understanding, not only of the benefits that medication may bring but also of the harms, which may be caused by medication use in general.

GPs realised that NSAIDs in particular were not the safest drugs to prescribe in the way that they had been and that patient safety and quantification of risk were key factors to be considered when prescribing NSAIDs. Several GPs indicated that following the intervention, they were more likely to consider medication to be the cause of a serious adverse event (such as NSAID related MI) which previously they would not have been aware of or even considered attributing to the drug.

GPs also became more aware of the evidence-base supporting holistic management of T2DM, prioritisation of interventions in reducing cardiovascular risk, key therapeutic interventions and prescribing recommendations.

6.4.2.4 Wider Impact of the Intervention

The intervention was also believed to have had wider-reaching impacts on secondary care prescribing and patient care.

As well as informing decision-making, improved evidence-based knowledge apparently empowered GPs and they became more assured of their own prescribing decisions, and taking ownership of them. GPs felt better informed and equipped with accurate knowledge with which they could confidently challenge consultant prescribing recommendations and inappropriate patient requests.

GPs were able to convey relevant information underpinned by the evidence-base to patients when decision-making (in a manner patients could understand) and felt that they were in a stronger position when justifying prescribing choices.

There was a considerable benefit on patient safety perceived, particularly because of a reduction in inappropriate use of oral NSAIDs. GP Comments on the wider impact of Intervention are summarised in Table 6.7

Impact on Knowledge, Awareness and Behaviour	
GP knowledge and behaviour	• Depending on your age, but the pharmacy, the therapeutics that you get as a doctor is very basic… I mean I've never had any therapeutics training… Since I qualified really, apart from what you pick up. (Post-1) • I think therapeutics is actually something very badly taught to medical students and something that's quite dear to my heart. Up until this year ***** University weren't even getting any pharmacology lectures (Post-6) • I don't have that diabetic experience to… it's, you know, new medications are coming onto the market, are you comfortable with managing this within General Practice? (Post-9) • I'm sure we're better and more evidence-based in those areas (Post-5) • Yeah, it did. It definitely did come out that it was evidence-based. (Post-7) • it probably renewed my vigour for finding alternative ways of treating people. And also actually not treating them at all (Post-4)
Raised awareness	• But then things like, you know if it has increased the risk of heart disease you wouldn't necessarily have noticed that. I mean the GI bleeds are a fairly obvious link but… (Post 5) • It was really the Pharmacist stressing the cardiovascular, you know, effects and, so I think I'm much stricter with my Type 2 diabetics about getting that under control because I, you know, now that I'm aware that that is the prime, the number one thing to do really. (Post-9) • I remember her 'hand'. That's always stuck in my mind, so, you know, that was useful and actually sticking in my mind thinking, made me think, "What is the most important thing we're doing managing diabetes?" and that was very useful. (Post-11)
Wider Impact	• When (the consultant) diabetologist came to present his community diabetes project it was all about HbA1c and I said, "Oh but the UK study showed that actually blood pressure's more important and you haven't even mentioned that, and that shut him up for a bit". (Post-11) • I feel much more confident within my practice of saying to a patient, for example, with the topical non-steroidals the evidence is this is as good as that. (Post-9) • for instance having the evidence base, for instance an ACE-inhibitor probably would be more protective against a sartan, is a very useful thing to be able to say to a patient (Post-11) • Of course with the diclofenac I mean it made us aware of the risks… …and we improved in a way, improved their care because we took a lot of patients off, or we are just prescribing naproxen if needed. (Post 10)

Table 6.7 Summary of GP Comments on Wider Impact of Intervention

6.4.3 GP Reflection

6.4.3.1 Reflection on Prescribing Practice

A number of factors had undoubtedly contributed to collective behaviour change. The process involved in generating individual behaviour change was less clear. The GPs believed that changing individual 'habitual' prescribing practice was not necessarily an easy thing to do. However, interactive discussions and the group dynamic apparently supported the individual in 'breaking the habit' and changing prescribing behaviour.

- it's because there's a habit you have to break (Post-7)

The GPs frequently referred to reflection as being part of the process involved in assimilating a complex array of facts and information resulting from intervention visits. They clearly reflected on their personal prescribing behaviour whilst collectively exploring justifications and motivations for prescribing change.

The opportunity to reflect on prescribing practice, consider options and ultimately to agree and take action collectively, was regarded as a more rigorous approach in achieving change.

6.4.3.2 Internalisation

Several GPs indicated that following personal reflection, they had 'taken on board' or internalised key messages and consequently had changed their prescribing behaviour. Individual GPs indicated that the intervention process had resulted in incorporation of evidence-based information into their personal prescribing decisions. Several GPs believed that they had become 'better prescribers' as a consequence.

GPs interactions with each other appeared to reinforce reflection, collective decision-making, and actions agreed by all, which may ultimately have created a more powerful means of implementing behaviour change than one-to-one interactions.

GP Reflection	
Reflection on Prescribing Practice	• Sitting around a table and actually, you know, dissecting it like that, you know, it makes us reflect on our practice so it has been useful. (Post 8) • as a consequence, you can be convinced or otherwise and therefore, we can make much rigorous action as a team to take it forward (Post-7)
Reflection about EBM in General	• But you know, this study allowed me to be reflective about it (EBM) and think well these are, this is the evidence base and maybe I should, you know, take that seriously and have a little look at that and, and try re-prescribing in a different way. (Post-9) • Yes, I think it has because it's made us... all just a little bit more thoughtful, in terms of our prescribing decisions. (Post-1)

Table 6.8 Summary of GP Comments on Personal Reflection

6.4.3.3 Reflection about EBM

In addition to raising awareness of the evidence relating to NSAIDs and T2DM, the intervention also apparently promoted some self-reflection on the principles of EBM and incorporation of evidence in decision-making in general. Increased awareness about availability of research evidence to inform prescribing decision-making encouraged several GPs to contemplate the importance of considering 'all the facts' when making individual prescribing decisions rather than prescribing routinely or based on habit.

Several GP comments on personal reflection are Summarised in Table 6.8.

6.4.4 Benefits of the Intervention Approach

There were several factors inherent in the intervention model which GPs found beneficial in support provision of prescribing support.

6.4.4.1 Independent Review

Having an ‘’external’ person with the skills and expertise to provide independent review and interpretation of practice prescribing data who could also facilitate and support the practice in implementing change was also regarded as an important factor. GPs appreciated that the intervention was tailored to the practice requirements and that the pharmacist was instrumental in evaluating their needs and providing relevant support.

6.4.4.2 Face-to-Face Meetings

Face-to-face meetings were regarded as a more effective means of communication than traditional interactions with MMT.

A dedicated forum, facilitated by a ‘specialist’ in prescribing issues enabled GPs and pharmacists to participate in regular dialogues about prescribing practice which GPs would not normally have considered themselves and otherwise simply would not have happened.

- I don’t think we’d have had any of the discussions we had around prescribing had we not been prompted by the Pharmacist (Post-4)

The GPs were able to explore prescribing issues in more depth and complexity than they would have done themselves or during APMs, which they believed added another dimension to their knowledge and understanding of issues and the topics discussed. The interactive nature of the meetings was also considered important in aiding the learning process and retention of information. The group dynamic was fundamental to the process.

Practice visits enabled clinically orientated discussions. GPs clearly valued the opportunity to ask, and have questions answered at the time by someone with the appropriate knowledge. GPs acknowledged that the pharmacists also possessed skills (which they did not), in accessing further information and relevant evidence, which also relieved GPs of having to seek information to answer clinical questions themselves.

6.4.4.3 Prescribing - Data

Benchmarking data enabled GPs to compare their prescribing with other practices, identify differences and to consider where to focus discussions on prescribing issues. Individual practice prescribing data raised awareness of GP prescribing, providing a true indication of prescribing within the practice. Many GPs discovered that they were not prescribing as they thought, either individually or as a group. Much greater understanding of practice GP prescribing habits and decisions developed as a result of meeting discussions.

6.4.4.4 Ongoing Feedback

Ongoing feedback, particularly regular trend data was considered crucial in enabling the GPs (and pharmacists), to target efforts at improving prescribing practice, to monitor against agreed actions and to demonstrate prescribing change over time. Both 'positive' and 'negative' feedback was considered useful as it was either motivational or enabled them to target further action.

6.4.4.5 Supporting Information

The GPs noted that clear and relevant presentation materials (referenced) were used in delivering key evidence-based messages. They observed that there was a breadth and depth of information incorporated in the presentation materials (detail aids), which had probably involved considerable effort to compile.

Several GPs received visit reports and read the pre-appraised evidence summaries provided by the pharmacists (e.g. MeReC). These were regarded as very useful summaries of the evidence-base underpinning the topics discussed.

A selection of interviewee comments on the benefits of the intervention to them are summarised in Table 6.9

6.4.4.6 A Different Experience for GPs

The GP experience of the intervention was considerably different from traditional communications with members of the MMT. Provision of prescribing advice as delivered through the intervention was a form of prescribing support which none of the GPs had previously experienced.

- Well, we didn't have anything like that before. (Post-4)
- Well we haven't had any prescribing advisors in before, not in this way (Post-13)
- As I said, that we felt more supported (Post-10)

Several GPs indicated that they believed they were actually being convinced to change their prescribing practice rather than being told what to prescribe. Overall, intervention visits were regarded as a positive experience.

- I think it felt a lot more positive. (Post-6)

Benefits of the Intervention Approach - GP Comments	
Independent Review	• And, an outside person can, if they get you together, you can alter how you do things as a practice really. (Post-1) • having a Pharmacist really look at our prescribing and the way it is actually matching up with the guidelines is very useful (Post-8)
Face-to-Face Meetings	• It's a face-to-face meeting, so that, in itself, is a very valuable thing for all people. We work so much better in that situation rather than just being sent an e-mail (Post-7) • I'll just come back to the um, sort of the way it was interactive. That's what was different (Post-3) • I don't think we'd have had any of the discussions we had around prescribing had we not been prompted by the Pharmacist (Post-4) • And always when you are at a meeting and you chat things over you are more likely to retain it than sending me an e-mail saying please use x,y,z. So, it was useful (Pre-7) • I think there is enormous value of having a meeting every so often, to get all the GPs and prescribers in a room and talking (Post-11) • But it was good to kind of…'*the Pharmacist* 'being there, we could just ask you questions and it was solved just there and then. (Post 13) • It was great that 'Pharmacist' came in face-to-face and brought the evidence that we asked and no question was out of limits really.Post6 • We had an opportunity to ask her areas that we were uncertain about and if she didn't know, she went away and researched and came back with some really good answers, which was fantastic, um, that was really helpful actually. (Post-7) • I mean it was, of course it's easier for us if someone comes and talks about it and presents it, as trying to get the information on your own, internet. (Post-10) • Therefore, we can make much rigorous action as a team to take it forward. So that's a definite, definite difference (Post-7) • Yeah, I think, yeah, this is much more useful now than PQP. (Post-7)
Prescribing - Data	• this is you know how you're doing compared to other Practices which is always an incentive to do more when you realise when you're one of the worst in the patch at something (Post-5) • Well interesting with the NSAIDs, we weren't doing what I thought we were doing as much as we said we were doing. (Post-1) • "Oh, no, no, we always use Naprosyn" and then he said "Well, actually, you know, you aren't" (Post-1) • the thing about being in a group of course is that people talk about their own prescribing habits and you start to understand how other people are prescribing and not just you as an individual, the way things are, are sort of done. (Post-3) • So there was the data that was also quite important to know how we are doing because you can see, compare yourself with the other peers (Post-10)
Ongoing Feedback	• It was useful when it was positive because we felt as though you were all doing well, you know. It's that pat on the back thing really (Post-5) • she provided, graphs and stuff, we actually saw the impact of the work that she was doing within the practice. (Post-9) • She went away and thought about what we needed and came back with appropriate data and stuff for us. (Post-9)
Supporting Information	• she's got a lot of information at her fingertips (Post-7) • There was a very good hand-out about diabetes that he gave us. Yeah, that was excellent (Post-1) • I think those things were useful 'cause they were like a summary I think, of all the information you'd found (Post-13)

Table 6.9 Summary of GP Comments on Benefits of Intervention Approach

6.4.5 Pharmacist Support

The GPs described visits as supportive and conciliatory rather than being directional or prescriptive. Discussions facilitated by the pharmacists were regarded as informative and evidence-based, compared with traditional interactions with MMT. Discussions were also more clinical, which GPs felt was relevant to their actual prescribing function rather than focusing on cost-reduction.

Meeting format was relatively informal. GPs found the approach more personal, and there was reciprocal communication between them and the pharmacist who was helping them achieve prescribing objectives. The pharmacists were all regarded as being clinically aware and, providing reasoned arguments, whilst also being prepared to listen and acknowledge GP concerns, which were taken seriously.

The GPs felt that communications with them were on a more professional level and that they were working in partnership with the pharmacists rather than MMT adopting a ‘policing role' as in traditional interactions.

Several GPs acknowledged that it had taken the pharmacist to make them realise and persuade them that change was required. The pharmacist had supported and even motivated some GPs into developing and implementing their agreed actions.

6.4.5.1 Pharmacists Delivering the Intervention

The GPs realised that the pharmacists delivering the intervention were acting in a very different capacity from other MMT pharmacists with whom they had previously interacted. They were perceived to be relatively senior, having influence in the wider medical community, and with means of instigating change at higher levels and across the primary/secondary care interface if necessary.

The pharmacist was considered fundamental to the success and impact of the intervention, not just as a conduit of knowledge about drugs and therapeutics but also as a skilled facilitator and guide, helping the GPs to achieve their shared goals.

The GPs recognised that the pharmacist had considerable expertise and knowledge (which they lacked) and the pharmacist became regarded as a trusted source and vector of reliable information, ultimately gaining considerable respect from the GPs. Many practices developed established relationships with their pharmacist, which were sustained following completion of the study. Overall, GPs were unanimous that the individual delivering the intervention should be a pharmacist essentially because of their specialist knowledge-base which is fundamental to their expertise.

Virtually all feedback regarding the pharmacists and their interactions with the GPs was positive and complimentary, in terms of their knowledge, skills and other attributes. The pharmacists were perceived as acting with professionalism and dignity and were trusted in their interactions with the GPs.

Although the pharmacists challenged GP prescribing practices, the outcome was a positive experience for GPs in terms of interactions with the pharmacists and the resulting impact on their prescribing behaviour.

The abilities and competencies demonstrated by the pharmacists inherent in the intervention model are multifaceted, requiring a combination of expert knowledge, which is both clinical and contextual in terms of the setting in primary care. The pharmacists clearly demonstrated excellent communication and facilitation skills with abilities to engage with clinicians in practice. Relevant experience, expertise and confidence were necessary to underpin and ensure success of the intervention.

A selection of interviewee comments relating to the intervention pharmacists are summarised in Table 6.10.

Pharmacists and the Intervention - GP Comments	
Pharmacist Interactions with GPs	• You know, um, it was a very give and take situation and, and she was, you know, prepared to give you the evidence and explain to you why she thought these things were better um, but also listen to you when you expressed some of your concerns about it. (Post-9) • It was much better and you felt it was more on a professional level rather than you're the underdog being told what to do, does that make sense? Which I know is probably a bit pathetic as GP's but…(Post-6) • I think that's absolutely fine and most of us can take it on the chin thinking, "Oh God, what an idiot, have I been doing that?" you know, so, so yeah, it's true. (Post-1) • I've no qualms therefore doing whatever I'm told, or working with them on something because that's the relationship we've got. (Pre-7)
Pharmacist Expertise	• It's not something you can do sort of fresh out of Pharmacy School…and you know it takes quite an experienced person I think to be able to facilitate it and to help you. (Post-5) • I think, from some of the other doctors, there is a realisation that, actually, you know these people have got something useful to say. (Post-7) • And I think because, because we were, because the partners were obviously hearing all this from the pharmacist they were really open to it. So I think it's had a very positive effect. (Post-6)
Skills and Competencies	• I think having somebody there giving you that guidance it's fantastically helpful. (Post-9) • I found 'the Pharmacist' to be a very competent, helpful adviser actually (Post-6) • You know, they haven't got all the answers, but, they can stimulate discussion. They, they can help us take forward what we're *all* trying to achieve, which is sensible prescribing. And they're not necessarily um, the enemy just beating you with a stick. (Post-7) • Well they know what they're talking about, yeah. (Post-1) • And actually 'the Pharmacist' was great, she's very good at what she did. (Post-6) • Oh, she was excellent, and she was very experienced, very knowledgeable. (Post-7) • I mean our Pharmacist was fantastic and we, you know, I think as I e-mailed to you. (Post-9)

Table 6.10 Summary of GP Comments on Interactions with Intervention Pharmacists

6.4.6 Value of the Intervention

Overall the GPs were extremely positive about the intervention and believed that it was of great value to them in supporting better prescribing behaviour.

All of the GPs interviewed post-intervention were receptive (if not enthusiastic) to the idea that intervention approach be expanded, both in terms of therapeutic areas and geographically. Many GPs believed that the approach, if implemented more widely would add further value by promoting better prescribing practice throughout the PCT. (Comments summarised in Table 6.11)

Value and Wider Implementation of the Intervention - GP Comments	
Value of the Intervention	• No, I think the intervention was excellent. (Post-6) • And overall I think it was quite positive, yes, I found it quite useful. (Post-8) • Some people said it was really excellent, it was really useful. I definitely thought it was useful. (Post-7) • You know. It's been of benefit, you know, I view any kind of education process to us as of benefit to the practice and… and to us (Pre-7)
Wider Implementation	• I think there's an important role personally for Medicines Management to come and do that and would be valuable. (Post-1) • I think there's no doubt it would be very useful. Having a Pharmacist really look at our prescribing and the way it is actually matching up with the guidelines is very useful (Post-8) • It is a service that I think, that would be good to continue, and I would have hoped that had shown enough benefits within the practice for it to be effective. (Post-9)

Table 6.11 Summary of GP Comments on Value and Wider Implementation of the Intervention

The intervention model was regarded as an appropriate if not ideal format and structure to discuss prescribing issues. GPs identified several elements of the intervention, which they had not previously experienced which they found particularly useful in supporting their prescribing objectives.

Allocation of a dedicated Prescribing Adviser with relevant skills and knowledge enabling GPs to establish relationships with one key individual was deemed important in providing regular and consistent prescribing support.

GPs envisaged regular meetings (between quarterly and annually, depending on practice needs) focusing on several aspects of prescribing which had been identified as requiring pharmacists input. Provision of evidence-based prescribing information was also regarded as a key component for the GPs. Regular meetings were considered important to reinforce messages, monitor prescribing activity and evaluate the impact of agreed actions.

- "these are the things that I'm thinking about, then you would do a meeting and you'd have all the evidence, all that sort of thing ready, and then three months later, you come back (Post-6)
- You'd sit down at the beginning of the year, you'd say these are our areas of prescribing that we need to focus on and then you'd have some subsequent meetings that would drill down into those areas a bit more. I like the idea of at least once a year just whizzing through a whole BNF as well just so everybody's aware of what's going on. (Post-3)

Provision of regular trend data was regarded as crucial in informing GP prescribing practice, to target efforts at improvement and to demonstrate prescribing change. Attendance by all practice GPs where possible (and other HCPs if relevant) was considered important to provide the opportunity to engage with and deliver key messages to all.

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6.4.7 Potential Barriers to Implementation

The main potential barrier to successful implementation of the intervention identified by GPs was lack of engagement either by individual GPs or by complete practices.

Lack of attendance by practice GPs (and other HCPs if relevant), for whatever reason was also believed to constitute a potential barrier. GPs believed that attendance by all practice GPs where possible would provide the opportunity to engage and to deliver the key messages to all.

Several potential 'enhancements' in provision of prescribing support were also identified during interviews and are considered further in the main Discussion. (Summarised in Table 6.12)

Suggested Gaps in MMT Support for GPs	
Evidence Updates	• Provision of regular pre-appraised evidence summaries highlighting key messages (maximum A4 sheet). • Raise GP awareness of evidence-based guidance as it becomes available.
Educational Support	• Address lack of GP knowledge. Provision of tailored sessions • Promote evidence awareness underpinning prescribing recommendations. Improve clarity and understanding • Ad hoc educational support depending on practice/PCT needs
Trusted Websites	• Develop list of trusted evidence-based resources to guide GPs to evidence-based sources of information on prescribing.
Up-to-date MMT website	• Post information on prescribing topics and recommendations. • Provide simple summaries with links to more in depth information.
Telephone advice line	• Capitalise on prescribing adviser skills in accessing and evaluating evidence and answers to clinical questions
Prescribing Lead	• Develop practice GP Prescribing Lead Job Description and Role Specification

Table 6.12 Summary of Suggested Gaps in Provision of MMT Services to Support PCT Prescribing Objectives

6.4.8 Wider Implementation

Several GPs indicated that participation in the study had provided insight and an opportunity to consider how they might work with MMT in the future. GPs realised that there was an untapped resource and expertise available within MMT which was not routinely being accessed to support their prescribing activities or promote evidence-based practice.

The intervention had raised awareness of the support or 'services' that MMT could offer which had not previously been routinely provided. Indications were that GPs attitudes to MMT had changed as a consequence of the intervention and that rather than being perceived as a barrier, MMT was regarded as a resource which could be accessed for support.

- I think, as I said, I think it's perhaps, it's given us an idea as to how we can um, interact as a practice with Medicines Management in the future. Er hopefully perhaps more fruitfully. (Post-3)
- I just think people are not seeing them as, er as an obstacle, as a difficulty. They're trying to use them you know. Other partners and doctors have realised that there is someone they can call on for help. (Post-7)

Affordability and resources, particularly in the forthcoming era of primary care commissioning were considered to be factors which should be considered if such a 'service' were commissioned through MMT and which may also impact on the frequency of meetings. It was also thought that results from the study might inform future decisions regarding commissioning medicines management support for GPs.

6.4.9 Summary

The GP experience of the intervention was different from traditional interactions with MMT in that it was regarded as supportive in helping them to achieve practice prescribing objectives collectively. The approach was educational and GPs found several facets and elements inherent in the intervention model beneficial in supporting their learning needs around evidence-based prescribing.

The intervention highlighted GPs lack of knowledge and understanding about medicines. Virtually all expressed their belief that the intervention had influenced their personal prescribing behaviour and that, their basic knowledge and education about drugs had increased. Importantly there became an increased awareness of safety and efficacy issues related to medicines use.

The intervention also apparently promoted self-reflection on the principles of EBM and incorporation of evidence into prescribing decision-making.

Overall GPs were extremely positive about the intervention which they believed was effective in influencing their prescribing behaviour. It was believed to be valuable to them and ultimately of benefit to the patient.

Several aspects of this review are explored further in the discussion section of Chapter 7 in conjunction with other study findings.

Chapter 7

Discussion

7.1 Overview

The main tenet of this study concerns getting research evidence into practice through an intervention aimed at influencing GP prescribing behaviour. It was designed primarily to demonstrate an impact on prescribing outcomes. It was also intended to establish whether there were any effects on patient outcomes, as evidence is currently lacking for both. The qualitative evaluation explored GP perceptions of EBM and the impact of the intervention from their perspective.

This chapter provides a summary and discussion of key study findings from both quantitative and qualitative evaluations. It considers reasons why the intervention was successful with reference to the current literature and known strategies (including several conceptual models) on getting research findings into practice.

This section also reflects on study strengths and limitations and considers how the intervention might be implemented more widely.

7.2 Key Findings

This study has demonstrated that implementation of the intervention using a multifaceted approach consisting of strategies which are known to work in changing healthcare professional behaviour has resulted in a change in GP prescribing practice and promoted the uptake of research evidence into practice.

7.2.1 Quantitative Evaluation

7.2.1.1 Prescribing Data – Outcome Measures

The most important finding based on quantitative evaluation of prescribing data demonstrated statistically significant differences in prescribing and achievement of primary outcome measures (defined prospectively and which determined the power of the study) aimed at improving uptake of evidence-based prescribing by GPs in the intervention group compared with control. This finding provides evidence for the impact of primary care pharmacists in promoting the uptake of research evidence into prescribing decision-making.

NSAIDs

Results clearly demonstrated statistically significant differences between intervention and control groups in the prescribing of NSAIDs.

A statistically significant difference in the primary outcome measure of a reduction in diclofenac ($p<0.05$, Mann Whitney U test) was demonstrated. Additionally, there was a statistically significant reduction in prescribing of COX-2 Inhibitors ($p<0.001$) and a corresponding and statistically significant increase in the prescribing of naproxen and ibuprofen combined ($p<0.05$). Effect sizes for each indicator were either medium or large. Naproxen and ibuprofen were recommended alternatives to diclofenac and COX-2 Inhibitors. However, naproxen appears to have been the preferred choice, possibly because it is associated with greater efficacy.

Individual and aggregated practice trend data graphs also demonstrate that there was a widespread reduction in the prescribing of diclofenac in the majority of intervention practices with a corresponding increase in naproxen.

Differences in the prescribing of total NSAIDs almost reached statistical significance ($p=0.057$, Mann-Whitney U test). The overall results, (from ePACT, individual practice data and GP feedback) also indicate a general downward trend in total NSAID prescribing in intervention practices.

T2DM

Statistically significant differences for the primary and secondary outcome prescribing measures for T2DM prescribing (increase in metformin and reduction in glitazones respectively) from ePACT data were not demonstrated.

One factor which affected glitazone prescribing and potentially the study results was the withdrawal of one of only two licensed glitazones (rosiglitazone) during the intervention period, for safety reasons. This event was obviously outside control of the study and would have necessitated review of individual patients and consideration of alternative therapeutic options which ultimately may have influenced prescribing patterns across the PCT.

Lack of major differences in prescribing of oral medications for T2DM may also reflect the long term nature of the condition and/or external influences on prescribing in T2DM such as diabetes specialist nurse and hospital prescribing.

Prescribing trend data presented in graph format also reflect results from statistical analysis of prescribing data.

7.2.1.2 Patient Related Outcome Measures

The results from the patient-oriented outcomes data also demonstrated statistically significant differences between intervention and benchmark groups. This finding challenges one of the main criticisms of EBM, which is that evidence is lacking to demonstrate that incorporation of evidence-based research into clinical decision-making improves outcomes for patients.[8,25,38]

Although a statistically significant difference in prescribing of metformin was not detected from ePACT data, a statistically significant difference in the proportion of patients with T2DM prescribed metformin in the intervention group compared with benchmark group practices was detected from practice data ($p<0.05$), indicating that metformin prescribing had increased, (also reported by several GPs during interviews). This result may have reflected more appropriate prescribing through initiation of metformin in newly diagnosed patients and/or possibly in previously diagnosed patients not already on Metformin, resulting in a greater proportion of patients being prescribed metformin overall. This trend is also reflected in individual practice data where prescribing of metformin increased in the majority of intervention practices.

There was also a statistically significant difference in the proportion of patients with T2DM prescribed a Renin-Angiotensin drug ($p<0.05$), an important (evidence-based) clinical intervention for patients with microalbuminuria. This trend was also reflected in individual practice data where there was a relative increase in the

prescribing of RAS drugs in the majority of intervention practices and relative decrease in benchmark practices with a tendency to increased use of ACE-I compared with A-II-A in intervention practices. Importantly, higher proportions of patients with microalbuminuria were also achieving tighter blood pressure targets in intervention group practices compared with benchmark practices.

These results therefore indicate that GPs had internalised key messages about holistic management of T2DM and were focusing on aspects of care which impact on patient outcomes, in this case, conserving renal function. The results also signify that clinical decision-making in this situation was underpinned by the evidence-base.

Not only were statistically significant differences in prescribing in patients with T2DM detected from practice data, importantly there were also statistically significant differences in proportions of patients achieving, HbA1c targets ≤7.5% ($p<0.01$) and ≤9.0% ($p<0.05$) in the intervention group compared with benchmark. Again individual practice data also indicates clear improvement compared with benchmark practices.

Ironically, the key messages delivered by pharmacists, intended to improve cardiovascular risk focussed on management of blood pressure in particular rather than intensive management of blood glucose. No statistically significant differences were detected in cardiovascular parameters although the practice data suggested that there was a tendency towards better management of blood pressure in individual practices compared with benchmark practices, particularly in patients with microalbuminuria.

Nevertheless, HbA1c is the key clinical outcome measure used to monitor disease progression in T2DM as well as treatment efficacy and the results indicate that this aspect of care was being managed better and in line with evidence-based treatment recommendations.

Interestingly, there were no statistically significant differences detected between intervention and benchmark practices for NSAIDs patient-orientated outcome indicators (i.e. clinical risk factors). The main reason is believed to relate to small sample sizes in data sub-sets for patients receiving NSAID medication compared for example with patients with T2DM.

The proportion of patients receiving NSAIDs in most practices is generally lower than the proportion of patients diagnosed with T2DM (approximately half). NSAID prescribing also reflects acute as well as repeat prescriptions whereas most prescribing in T2DM consists of several repeat prescriptions for what is a long term condition. Therefore, the overall volume of NSAID prescribing is likely to be lower than prescribing for patients in T2DM and differences in patient sub-sets harder to detect from practice data.

Conversely, NSAID patient-orientated prescribing outcome indicators do suggest an increase in prescribing of PPIs and a reduction in prescribing of concomitant aspirin in patients on NSAIDs in intervention compared with benchmark practices.

7.2.2 Qualitative Evaluation

7.2.2.1 Pre-Intervention Interviews

The main finding arising from the exploration of perceptions, attitudes and beliefs regarding EBM suggests that the majority of GPs consider application of EBM as a model of practice to be applied in the clinical encounter, equated with 'best practice' in clinical decision-making. Results also indicated that despite enthusiasm to practice as evidence-based practitioners, GPs do not generally possess the skills to access or evaluate the evidence to inform their clinical decision-making and that RCGP curriculum competencies, aimed at ensuring evidence-based decision-making in everyday practice are not routinely applied or consistently demonstrated by GPs.

7.2.2.2 Post-Intervention Interviews

The main findings arising from post-intervention semi-structured interviews with GPs were that the intervention educated and supported GPs in improving prescribing practice in line with the EBM paradigm. GP knowledge and understanding of the evidence-base underpinning prescribing decisions increased and they became more confident in their prescribing decisions. Virtually all believed that the intervention had influenced their personal prescribing behaviour and additionally, promoted self-reflection on the principles of EBM and incorporation of evidence into prescribing decision-making. Overall GPs welcomed the intervention and were keen to receive further and regular prescribing support in line with the intervention model.

7.3 Translating Research Evidence into Practice

Until recently, the spread of evidence was regarded as a linear process involving changes in individual clinicians behaviour in line with evidence-based guidelines.[214,227] However the notion that research packaged as guidelines and the assumption it will be automatically used is now outdated.[221] Evidence indicates that getting research into practice involves significant and planned change involving individuals, teams, organisations and systems.[214,221,227]

One of the more recent advances in EBM is the emergence of Implementation Science, a movement dedicated to the study of methods to promote the integration of research findings and evidence into healthcare policy and practice (or knowledge translation).[226,227,228,229] Various models have been used to reflect translation of research into practice.

7.3.1 Evaluating Implementation of the Intervention

One such model, The PARiHS framework (Promoting Action in Research Implementation in Health Services) is a conceptual framework considered useful for researchers in framing their research or knowledge translation endeavours.[227,230]

The framework proposes that successful research implementation (SI) is a function (f) of the relation between the nature of the evidence (E), the context in which the change is implemented (C) and the mechanism by which the change is facilitated (F), expressed as: SI = f(E,C,F).

Each element is positioned on a low to high (or weak to strong) continuum. Most successful implementation occurs when evidence is scientifically robust and matches professional consensus and patient preferences (high evidence), the context is receptive to change with sympathetic cultures, strong leadership and appropriate monitoring and feedback systems (high context) and where there is appropriate facilitation of change, with input from skilled facilitators.[227,231]
Key features of the framework are summarised in Table 7.1.

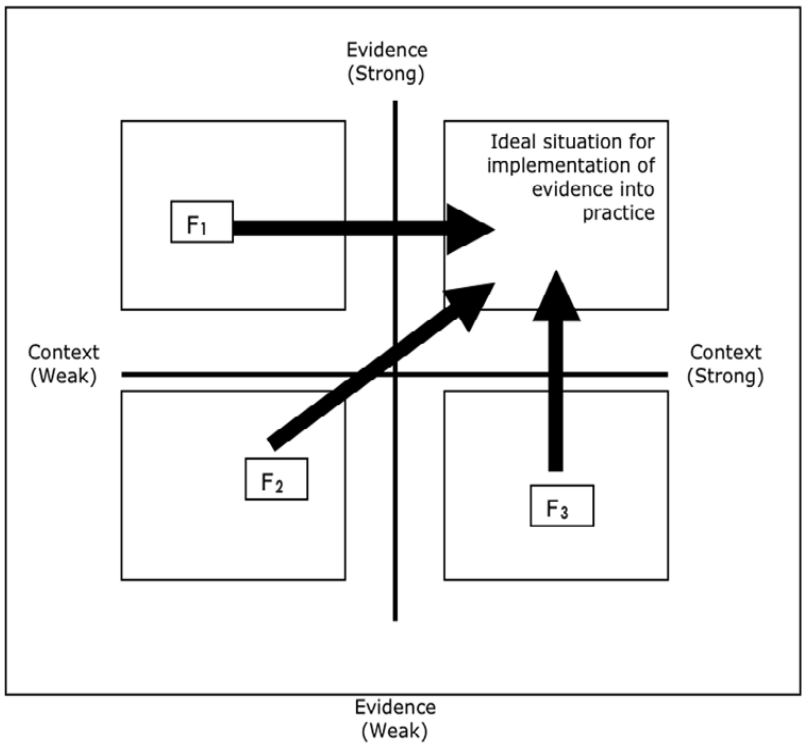
Main Features and Assumptions of the PARiHS Framework

- Evidence comprises codified and non-codified sources of knowledge, including research evidence, patient factors, clinical expertise
- Melding and implementing evidence in practice requires negotiation, developing shared understanding about benefits, disbenefits, risk and advantages of the new over the old
- Some contexts are more conducive to successful implementation of evidence in practice than others. These include contexts that have transformational leaders appropriate monitoring, evaluative and feedback mechanisms.
- There is an emphasis on the need for appropriate facilitation to improve the likelihood of success. The type of facilitation, the role and skill of the facilitator that is required is determined by the state of preparedness of the team in terms of acceptance and understanding of the evidence, receptivity of their place of work or context in terms of resources, culture and values, leadership style and evaluation activity. Facilitators work with individuals and teams to enhance the process of implementation.

Table 7.1 Main Features and Assumptions of the PARiHS Framework (Kitson)[227]

The framework may be applied retrospectively as here to assess interactions between evidence, context and facilitation in implementation settings. The (therapeutics-related) evidence presented to the GPs through the intervention constituted high quality research, critically appraised through robust and transparent methodologies, thus fulfilling the criteria for 'strong' evidence. With respect to Medicines Management, GPs were dissatisfied with the existing culture (suggesting weak context) although were ultimately receptive to change moving to strong context.

Facilitation in the intervention model may be represented as F1 in Figure 7.1.



F1 = facilitation method for transforming weak context and strong evidence to highly receptive context
F2 = facilitation method to manage weak context and weak evidence situation – (most challenging)
F3 = facilitation method to manage strong context and weak evidence situation

Figure 7.1 The PARiHS Diagnostic Evaluation Grid. (Kitson)[227]

The study results demonstrate successful implementation of the intervention. When evaluated against the PARiHS Framework, each individual element (evidence, context, facilitation) achieves a high rating. Monitoring and feedback systems (prescribing trends) were most appropriate for the intervention intended to influence prescribing (therefore also 'high context'). When combined, the overarching output suggests successful implementation against all criteria and, according to the framework indicates an ideal situation for implementation of evidence into practice. Importantly application of the model supports study results in that the means of facilitation was not only appropriate, but was highly effective.

7.3.2 Facilitation

Facilitation, the process of enabling (making easier) the implementation of evidence into practice is central to the PARiHS framework.[227,231] It was also central to delivery of the intervention.

Main features of facilitation according to the framework are summarised in Table 7.2

Features of Facilitation – The PARiHS Framework
• Facilitation is a process that depends on the person (the facilitator) carrying out the role with the appropriate skills, personal attributes and knowledge • The purpose of facilitation varies from providing help and support to achieve a goal to enabling individuals and teams to analyse, reflect, and change their own behaviours and ways of working • A 'facilitation continuum' has been described, which distinguishes between a 'doing for others' role (more discrete, practical and task driven) on one side to an 'enabling and empowering' role which is more developmental, seeking to mentor, guide and support staff within the system to take control of their own learning and change processes (holistic). • Facilitation skills are developed through experiential learning, and more recently through the acquisition of key facilitation competencies • Facilitation as a discrete intervention has been described in the practice development movement in nursing and in the quality improvement literature

Table 7.2 Features of Facilitation within the PARiHS Framework[227]

Facilitators require appropriate skills and knowledge to help individuals, teams and organisations apply evidence in practice, and to make sense of the evidence being implemented in the context in which the change is occurring. Depending on the level of facilitation required, (from task-based to holistic change), skills and attributes required of facilitators may vary.[231] Where implementation encompasses counselling and experiential learning, the facilitator's role involves enabling development of reflective learning by helping to identify learner needs, guiding group processes, encouraging critical thinking and assessing achievement of learning goals.[231]

Within the intervention, the prescribing advisers were clearly fulfilling a complex, multifaceted role as part of a holistic process aimed at changing prescribing behaviour and which, as confirmed in GP feedback, undoubtedly encouraged reflective learning and critical thinking by the GPs. The pharmacists also guided group interactions and processes, and supported and assessed achievement of agreed actions and (prescribing) goals.

Skilled facilitators may adjust their role and style depending on circumstances. A facilitator who elicits respect, is credible and empathic with a personal style characterised by flexibility and consistence also gives strong support for implementation.[11,231] GP feedback indicated that the pharmacists demonstrated all of these attributes during their interactions with them.

Within the Framework, 'high' facilitation (or strong support for implementation) relates to the presence of appropriate facilitation. Study results and GP feedback indicate that the pharmacists (with underpinning therapeutics knowledge and expertise), demonstrated well-developed facilitation skills in influencing prescribing behaviour and encouraging the adoption of evidence in practice, therefore supporting a 'high facilitation' score within the Framework.

The facilitator role, is fundamental to the success of implementation of the intervention. Not only do the study results suggest that the intervention as facilitated

by the pharmacists was successful, evaluation against the PARiHS framework also infers that they were operating at 'high' level and as effective facilitators in implementing evidence in practice.

7.3.3 Stages in the Intervention Process

Translation of research evidence into practice encompasses three major stages.[229]

- Knowledge creation and distillation
- Diffusion and dissemination
- Adoption, implementation and institutionalisation

In addition to deploying facilitation skills, preparation and delivery of the intervention to promote uptake of evidence-based prescribing by GPs, involved appropriately skilled pharmacists in each stage of the process. (Summarised in Table 7.3)

Translation of Evidence into Practice - Stages in the Intervention Process
Knowledge creation and distillation • Utilising mainly pre-synthesised evidence-based information accessed from reliable sources. • Key evidence-based messages further 'repackaged' for presentation to GPs as detail aids. • Prescribing data, tailored to each practice for monitoring and feedback prepared on a regular basis. • A 'library' of relevant evidence-based supplementary materials collated centrally for both GPs and pharmacists use. • All of these activities were co-ordinated centrally by the CI.
Diffusion and Dissemination • Primary care pharmacists delivering and facilitating delivery of the multifaceted intervention through practice visits. • Pharmacists acting in an educative role based on an academic detailing approach. • Dependent on pharmacists understanding the evidence and its relevance in the context of clinical decision-making and GP prescribing. • Dependent on pharmacists ability to manage a complex array of information which they were able to convey to GPs in promoting uptake of best available evidence into decision-making.

Adoption, Implementation and Institutionalisation
 	
• Provision of dedicated and tailored support to each practice by the allocated pharmacists.
• Pharmacist required appropriate facilitation skills
• Resulted in
  ○ collective decision-making and
  ○ commitment to agreed actions by GPs
  ○ agreed actions contributing to impact of the intervention.

Table 7.3 Translation of Evidence into Practice - Stages in the Intervention Process

7.3.4 The Intervention as an Innovation

The term 'Innovation' may be used to encompass a set of activities and behaviours aimed at translating research findings into practice.[214,232]

An extensive literature review of the uptake of research innovations defines the three principle means of spreading research findings in practice as diffusion, dissemination and implementation. Diffusion and implementation may be regarded as being situated at opposite ends of a continuum with dissemination being positioned somewhere between the two.[214]

- 'Diffusion' is passive, unpredictable, uncertain, in effect, 'letting it happen'.
- 'Implementation' is scientific, orderly, planned, properly managed and requires active efforts to 'make it happen' by mainstreaming or embedding innovation within organisational systems and structures. Its influence is top down and takes much effort at a higher level to bring about.
- 'Dissemination' involves 'helping it happen' using active and planned efforts to persuade target groups to adopt the innovation. It is negotiated, influenced and enabled.

Pre-intervention feedback from GPs indicated that they primarily regarded uptake of evidence in practice occurring through either Diffusion or Implementation. However the intervention tested in this project, clearly falls into the category of 'Dissemination' or 'helping it happen'. By raising awareness of evidence-based prescribing, and by facilitating and supporting change, GPs were persuaded (and convinced) of the evidence to inform decision-making and consequently the benefits both in terms of its application in clinical practice, and related benefits for patients.

In this context, by spreading research findings into practice through 'dissemination' the intervention may be described as an 'innovation'. It also fulfils the criteria under the definition of an innovation, summarised in Table 7.4. [214,232]

Definition of an Innovation in Health Service Delivery and Organisation
An innovation in health service delivery and organisation may be defined as ' a set of behaviours, routines and ways of working, along with any associated administrative technologies and systems' which are: • Directed at improving health outcomes, efficiency, cost-effectiveness or the user experience • Implemented by means of planned and co-ordinated action by individuals, teams or organisations. • Perceived as new by a proportion of stakeholders • Linked to the provision of healthcare • Discontinuous with previous practice
Attributes of an Innovation
An innovation is more likely to be adopted if possesses six key attributes. • Relative advantage over current practice which is clear and unambiguous • Lack of complexity (is simple to 'use' or can be broken down into simple components) • Compatibility (is compatible with the adopters values, beliefs, perceived needs and ways of working) • Trialability (Intended users can experiment on a limited basis before committing) • Observability (the impact is visible and obvious to intended adopters) • Re-invention. The innovation can be adapted to suit local needs and services
Adoption of Innovation at an Organisational Level
At an organisational level an innovation is more likely to be adopted if • There is a tension for change (staff feel that the current situation is intolerable) • The innovation is congruent with the organisational values, norms and ways of working • The innovation is supported • Implications have been carefully considered and planned for • Resources have been allocated • Monitoring systems are in place to evaluate its impact

Table 7.4 Summary of 'Innovations' Adapted from 'Getting a better grip on research: the organisational dimension'[232]

The intervention tested aimed to improve patient health outcomes by means of planned and co-ordinated action from within the medicines management service to promote evidence-based prescribing practice. It was new (certainly very different), and hence discontinuous with previous practice as GPs confirmed.

The intervention also possesses attributes which are more likely to promote its adoption in practice. Clear and unambiguous advantages to GPs, patients and to the organisation were demonstrated by both quantitative and qualitative study evaluations. Although the intervention is by definition 'complex', considerable effort was expended in clearly defining the component parts to ensure consistency of

approach and reproducibility. It is compatible with 'adopters' values and beliefs as GPs wished to practice in an evidence-based manner and appreciated the principles of incorporating research evidence into their clinical decisions. This study itself was an opportunity to pilot the intervention, providing evidence of its impact which is visible and obvious to intended adopters. GP feedback confirmed flexibility and tailoring to meet individual practice needs.

GPs expressed dissatisfaction with established arrangements for influencing prescribing practice and enthusiasm for receiving more support based on the intervention model. They were also positive and enthusiastic about adopting the intervention more widely. If the intervention were to be formally adopted at organisational level, it would be necessary to convince commissioners of its benefits including completing a cost-analysis and demonstration of cost-effectiveness.

7.3.5 Supporting Adoption of Evidence into Practice

Adoption of evidence into practice ultimately depends on decisions to change made by individual people. Adopting a strategic approach to introducing evidence and changing practice is recommended.[224] As with many 'innovations', development and implementation of this intervention required significant preparation and planning and consistent effort involving, individuals, teams, organisations and systems.[214,221,227]

Seven key principles which support adoption of evidence in practice have been identified for people whose job involves introducing evidence-based changes to practice.[224,233] It is argued that the intervention as employed also conforms to these principles as summarised and described in Table 7.5.

Seven Principles for More Successful Implementation of Evidence into Practice
1. Aim for adoption of the change in practice, not its imposition • The intervention clearly promotes adoption of change in prescribing, by using a targeted multifaceted approach to 'help it happen' by influencing behaviour rather than making it happen.
2. Consider the concerns and questions of potential adopters • Pharmacists supporting GPs in building on prior knowledge and developing understanding were able to address concerns and questions of potential adopters.
3. Make it easier for people to do the right thing • GPs realised that changing ways of doing things and breaking habits is difficult, even if individuals are motivated to do so. The intervention supported GPs in 'doing the right thing' by adopting several approaches known to influence behaviour within the multifaceted approach. The intervention also capitalised on GP motivations to practice as evidence-based practitioners within their practice environment.
4. Support effective foraging, hunting and hot-synching • The intervention supported effective foraging, hunting, hot-synching and information mastery primarily on behalf of GPs, also making it easier for them to implement change.
5. Recognise and support the communities of practice in which potential adopters work • By providing continuing support and facilitation, pharmacists assigned to individual practices were able to tailor support to GP communities of practice.
6. Allow potential adopters to experiment with and adapt the change in practice to their situation • The targeted intervention approach enabled potential adopters (GPs) and pharmacists to adapt change in practice to their situation.
7. Plan carefully but be flexible and adaptable • The intervention as a whole was carefully planned with discrete components defined, resulting in a consistent approach across the participating practices. However, there was flexibility in approach which was largely due to pharmacist skills in tailoring input with their allocated practices.

Table 7.5 Seven Principles for More Successful Implementation of Evidence into Practice

7.4 Clinical Reasoning How People Make Decisions

Understanding how people learn and make decisions is also relevant in translating research evidence into practice, and using approaches which include measures to support personal adoption of evidence, as in this intervention, may be advantageous.[224]

Healthcare professionals need to be good decision makers. Recent work suggests that if students understood the importance of reasoning processes in clinical decision-making they might be better equipped to adapt their reasoning strategies as the situation demands.[234] Better understanding of reasoning and decision-making processes ought also help reduce errors and increase proportion of decisions which are better.[226,235] Unfortunately, learners are rarely exposed to the evidence that describes how humans make decisions.[222,226]

7.4.1 Dual Process Theory

Background

Cognitive processes which underlie clinical reasoning, are complex and multifarious. Dual Process Theory is a model of reasoning and decision-making which applies to all types of decisions including medical decision-making. [236,237] The theory characterises two systems of acquiring information and reaching a decision. (Summarised in Table 7.6). The principle modus operandi of the model is pattern recognition.[236]

Dual Process Theory in Clinical Decision-Making

• System 1 is based on intuitive reasoning and is reflexive, fast, frugal and effortless, with low to variable reliability.
  ○ Relies heavily on the experience of the decision-maker. Experienced decision-makers recognise overall patterns (Gestalt effects).
  ○ Characterised by heuristics and other mental shortcuts. Many diagnostic decisions often based on this type of pattern recognition.[237]

• System 2 is based on analytical reasoning and is deliberate, rule-based, time consuming with high and consistent reliability.
  ○ Takes place under more ideal conditions where there are fewer boundaries and greater availability of resources, resulting in less uncertainty.
  ○ Engaged when patient's signs and symptoms not readily recognised or do not follow a particular script (illness script).[237]

• Both processes may interact with each other so final output is a synthesis of the two.

Table 7.6 Key Characteristics of Dual Process Theory in Clinical Reasoning

Traditional learning and development of expertise is essentially based on System 2 reasoning. It is logical, linear and largely hypothetico-deductive. As experience grows, a System 1 approach starts to dominate as pattern recognition develops.[223]

Development of new skill (e.g. prescribing particular drug) can also be illustrated by dual process theory in combination with the conscious competence model.[226,235] Summarised in Table 7.7

Development of Clinical Expertise
• Initially, learner knows they are not able to do it (consciously incompetent)
• Purposeful and conscious learning is required (using system 2 processes) to a state of conscious competence
• With further practice, actions may become automatic, moving towards unconscious competence. System 2 learning has become embedded in System 1 process.
• If person stays in System 1, errors may occur (a state of) unconscious incompetence. By effortful System 2 assessment, can realise this and become consciously incompetent, again using System 2 as a check on system 1.
• A fifth stage is proposed whereby an unconsciously competent practitioner can toggle into System 2 and perform an internal assessment using reflection or metacognition to correct activity.
• Development of expertise and traditional learning is almost all System 2

Table 7.7 Development of Clinical Expertise based on Dual Process Theory and the Conscious Competence Model

System 2 reasoning might be anticipated to underpin most healthcare decisions. However, clinical-decision-making requires recall and interpretation of large volumes of information. Because there is a limit to the amount of information which humans can process, it becomes truncated so as to make 'good enough' decision (satisficing). The tendency is therefore for the system to default to that requiring the least cognitive effort, that is, System 1 (the 'cognitive miser' function). This approach may carry risks if the relevant information is not incorporated. Most decision errors occur in System 1.[238]

Clinicians mainly access information to inform decision-making through reliance on mindlines, informed by brief reading, and developed and reinforced through experience, repetition and interactions with others in the community of practice.[4,40,41,224] This approach relies on System 1 processing.

Gaps between evidence and practice can occur when clinicians develop a pattern of knowledge which is relied upon for decisions using System 1 without the activation of System 2 check. Metacognition, the ability to step back and reflect on what is going on in a clinical situation is essentially System 2 monitoring in action and is not necessarily activated.[236,238]

In most areas of therapeutics, it is possible to identify a difference in patterns of prescribing by UK GPs based on System 1 processing and what the System 2 approach, based on the evidence would indicate is optimal.[223]

7.4.1 Discussion

Results from semi-structured interviews indicate that with respect to prescribing decisions, GPs prefer to 'stick with what they know' favouring and relying on a largely System 1 decision-making mode.

Dual Process Theory may therefore offer some explanation as to why GPs prefer not to move from their 'comfort zone' into an analytical System 2 approach which requires careful rational analysis (including metacognition), evaluation of all the information, and which takes much effort and time. Instead, relying on predominantly System 1 processing for most prescribing decision-making.[224]

It is believed that Dual Process Theory, may also go some way to explaining the effectiveness of the intervention. It is hypothesised here therefore that through the intervention model, patient-centred decision-making based on best quality evidence is promoted by supporting a combination of System 2 processing (by pharmacists) for incorporation into System 1 decision-making (by GPs).

Evidence indicates that GPs rely on System 1 processes in prescribing decision-making. One component of the intervention depends on assimilation and evaluation of the relevant evidence using System 2 processes by suitably qualified pharmacists. Additionally, pharmacists delivering the intervention in practices, promoted evidence uptake by facilitating and in effect enabling System 2 learning by GPs, which ultimately became embedded in their System 1 processing, the GP preferred decision-making style.

It is proposed that this process of GP learning, as facilitated within the intervention by individual pharmacists is not only effective, it is also more efficient as it is conducted with groups of GPs in their 'community of practice'.

Understanding how people learn and make decisions and better manage information may help in developing strategies for implementing the adoption of evidence and changing practice.[214] Acquisition of knowledge in traditional teaching and learning, occurs where the learner gains knowledge in the teacher approved form ('push' approach). In contrast, adult learning theory encourages a 'pull' approach where learners are more in control of the learning process and teachers help learners build new knowledge and understanding from and onto prior knowledge.[224]

7.5 Learning as a Community of Practice

Learning can also occur through participation, which may be defined as a process of becoming a member of and contributing to the development of a 'community of practice'. The community of practice is also seen as having similar thinking, values, behaviours and expectations which are associated with its particular culture. A group of GPs in a practice would characteristically constitute 'a community of practice'. Learning in this model, enables creation of knowledge at the level of both the individual and the system in which they practice.[224] In this model, individuals engage in and contribute to the communal development of these concepts and the community's sense-making of new information or circumstances.

The idea of community of practice collectively making sense of new information and refining group characteristics can help explain complex behaviours of its member and its interpersonal influences within it.

The intervention model also facilitated GPs learning as a community of practice. It facilitated group decision-making, enabling pooling of intellect, expertise, and GP perceptions and fostering communication between participants so that all were involved and ultimately accountable for the group actions. 'Mindlines' are also developed and reinforced through experience, repetition and interactions with others in the community of practice. Interaction with GPs through the intervention approach also capitalises on the 'mindlines' model of learning by functioning in an environment where discussion and joint decision-making is based on accurate information and robust evidence (rather than unreliable sources).

7.6 Awareness of the Evidence

In the absence of a mechanism to raise awareness of new and relevant evidence, GPs relying on System 1 processing are only ever likely to become aware by talking to colleagues or from brief reading which may ultimately serve to reinforce 'mindlines', which may reflect inappropriate practice rather than best evidence.[223] Such an approach constitutes a high-risk strategy as study results demonstrate that GPs do not have time or more importantly, the skills to evaluate information themselves which has mostly reached them opportunistically, rather than through a robust process to deliver high-quality evidence-based information. It is also unlikely to result in implementation of best evidence in clinical practice.

Better Information Management skills might offer individual GPs an alternative approach to access evidence-based information.[216,222] Ideally clinicians need to adopt a more systematic approach to knowing or being able to find the best available evidence on which to base practice. In many areas of medicine, evidence is already synthesised.[217] Unbiased summaries from trustworthy sources are widely available with information translated in a format that GPs and patients can understand.

Unfortunately, not only are GPs not skilled in formulating questions, literature search and critical appraisal, (hunting) which is System 2 processing, feedback indicated that neither are they skilled in managing information to ensure filtering and receipt of relevant and valid evidence which may influence practice (foraging). Consequently, GPs are unlikely to keep up-to-date and incorporate evidence into prescribing decision-making.

None of the GPs indicated that they received regular alerts from trustworthy sources. Techniques such as hunting, foraging and 'hot-synching' were not apparently part of their routine clinical practice.

The results suggested that there remains a major challenge for GPs in identifying and accessing important new evidence to incorporate into prescribing-decision-making and in highlighting information which is out of date and no longer appropriate.

In an environment of information overload therefore, one question is whether practitioners recognise when they do not have the best evidence for clinical decision-making? Research findings presented to GPs may be incorrect, review articles often fail to mention important advances and harmful treatments continue to be used.[222]

The GPs interviewed believed that they practiced in an evidence-based manner, which despite some evidence to the contrary, indicated that they might prefer that their clinical-decisions be made on a System 2 approach. However they indicated that they did not have the time or the relevant skills and reverted to System 1 processing, based on unstructured reading, professional networks and expert opinion.

Without an active strategy, relevant evidence to inform clinical decision-making is unlikely to reach GPs indicating that a different approach is required. The process of adoption of evidence into practice is a complex one and careful planning involving individuals, teams, organisations and systems is essential when promoting evidence uptake.

The intervention as described here is believed to constitute an effective strategy comprising an appropriate approach (or combination of approaches) to support adoption of evidence into prescribing practice in primary care and which is tailored to the environment in which adoption of evidence into practice is being promoted.

7.7 How the Intervention may Support Evidence-Based Decision-Making

Study results indicate that GPs do not have the skills nor apparently the inclination to access robust evidence to answer clinical questions and inform clinical decision-making in routine practice. Neither are they skilled in managing information to find best available evidence on which to inform practice.

The RCGP curriculum requires that GPs base their treatment decisions on best available evidence. However, the fact remains that for whatever reason, many GPs did not demonstrate required EBP competencies, which appeared to be more aspirational than a reality. GPs still failed to find or incorporate the best available evidence into their prescribing decision-making. Results also indicated that GPs are unlikely to address these responsibilities if left to their own devices. GPs were however keen to practice EBM and were enthusiastic about the intervention which supported them in promoting evidence uptake into prescribing decision-making and in becoming better prescribers. For organisations and individuals wishing to support best quality patient-centred decision-making in prescribing, then an effective process is clearly required. It is proposed therefore that the intervention which has been described here and shown to work, provides an effective means of promoting uptake of research evidence into prescribing practice.

Accessing and evaluating evidence is a highly skilled job. It is also the most difficult and time-consuming part of EBM. GPs are not equipped with relevant skills and their time might be better spent seeing patients. Medicines Management functions within primary care organisations typically employ pharmacists in distinct and specialist roles. Many primary care pharmacists are equipped with skills in critical appraisal, accessing evidence and answering clinical questions. Many also have developed information mastery skills enabling access to high quality evidence syntheses produced by organisations with robust and transparent methodologies such as Cochrane, NICE, SIGN, CKS and the NPC. Consequently, they are consistently aware of relevant information which they are also able to communicate to GPs and who might otherwise not receive the benefit of this expertise.[226]

In addition to dissemination of relevant evidence-based prescribing information to GPs, appropriately skilled primary care pharmacists may confidently challenge inaccurate knowledge and GP misconceptions which may have evolved through reliance on informal networks and their own inability to assess the value of information presented to them.

Delivery of this intervention would not have been possible without pharmacists with traditional EBM and information mastery skills as well as those with relevant skills, experience and expertise in facilitating delivery of the intervention. Clinical primary care pharmacists can fulfil functions in accessing finding the best available evidence and advice to inform prescribing decision-making. Importantly primary care pharmacists can support GPs in bringing about prescribing change as demonstrated in this study.

It is believed therefore that the intervention constitutes an effective means of promoting and influencing evidence-based prescribing with primary care pharmacists providing appropriate expertise and fulfilling the role of facilitator.

7.8 Study Strengths

The purpose of the intervention was to promote evidence-based prescribing practice by adopting a number of (evidence-based) approaches known to be effective in influencing behaviour change.

Several aspects of the study design and implementation are believed to have contributed to the impact of the intervention in influencing GP prescribing behaviour. Study design and development took into consideration MRC recommendations on design and development of complex interventions. These included standardisation of design and delivery of the intervention, and identification of its components. Although the main evaluation to demonstrate efficacy was quantitative, qualitative evaluation was incorporated to add depth and gain insight of the recipients of the intervention.

Cochrane recommendations were also addressed by utilising effective strategies (multifaceted approach, interactive educational meetings, audit, feedback, key messages summaries, clearly defined type of visitor and visit content) and by employing sustained efforts to improve prescribing behaviour. The study was powered to detect significant differences in prescribing and patient outcomes were also included as an evaluation measure. The qualitative evaluation also included a process review. Consequently, it is believed that study design and evaluation complied with robust, evidence-based recommendations to support adoption of evidence in practice and to address evaluation of a complex intervention.

The intervention constitutes a clearly defined consistent and reproducible approach, (component parts described) for promotion and implementation of evidence-based prescribing in practice and had produced evidence to demonstrate that such an evidence-based approach when adopted, works in influencing prescribing behaviour.

Importantly, the quantitative evaluation has provided robust evidence which was previously lacking to demonstrate the impact of prescribing advisers on GP prescribing by promoting incorporation of evidence into the prescribing decision-making process. Most significantly, evidence for an effect on patient outcomes which was also lacking (and which was one of the major criticisms of EBM) has also been demonstrated.

Several other aspects of the multifaceted approach inherent within the intervention strategy are also believed to have contributed to the overall effect in influencing prescribing behaviour in practice.

Changes in clinical practice are generally triggered by personal contact as in 'academic detailing', the approach which was employed within the intervention.[232] Interpersonal influence was fundamental to the intervention and pharmacists were central to its delivery.

Importantly, the intervention aimed for adoption of change, not its imposition. GPs were clearly persuaded and ultimately convinced to change prescribing behaviour. The AIDA adoption framework explains how clinicians may adopt an MMT agenda and describes four stages in the process:[11]

- raising *Awareness* of issues, evidence and potential changes to practice which
- leads to *Interest* to make some sort of change and engage with the process
- then making a *Decision* to change
- followed by *Action* to do so

Whilst this framework was not adopted prospectively as a strategy for GPs to conform to a predefined agenda, the process through which the GPs and the pharmacists progressed in achieving change within the intervention was similar, starting by raising awareness of the evidence and practice prescribing patterns, followed by discussion, decision and action to bring about change.

Building relationships is also an extremely important factor with prescribing advisers ideally striving to become a trusted adviser. The core of any such relationship must be based on trust and communication should not simplify and shift the argument in MMT favour by representing only half the evidence or guidance.[11]

The GPs believed that building a relationship was important and reported that relationships based on trust were established between them and the pharmacists. Feedback also indicated that this was a major difference between traditional interactions with MMT (which focused on cost-based arguments) and delivery of the intervention which was clearly evidence-based. Several GPs also noted that their pharmacist was empathic, acknowledging their concerns, without trivialising them, also important factors in interactions with clinicians.[11]

Gaining agreement was also an important factor in obtaining GP commitment to change. Clear and concise written feedback summarised as visit reports following all visits and regular and follow-up communications involving reinforcement of key messages and agreed actions and review of progress were also documented in visit reports. Employing sustained efforts (as recommended by Cochrane) to improve prescribing behaviour, rather than individual visits (as for APMs) was also believed to have been an important factor in achieving change. Clear communication materials, including concise detail aids and provision of prescribing data throughout the intervention period as part of the comprehensive evidence-based package intended to influence prescribing were all believed to have contributed to the overall impact.

7.9 Study Limitations

Ideally a randomised controlled trial would have been preferred to evaluate the impact of the intervention. However, because of the small sample size, this was not feasible. Instead, the preferred most robust alternative design, a pre-test, post-test study was adopted whereby a control (business as usual), non-intervention group with the same characteristics as the study population was identified for comparison and where observed differences are assumed to be due to the intervention.

The fact that the study was conducted in one PCT is also a potential limitation as a larger study involving other PCOs might reflect a wider more generalisable picture.

Potential limitations to success of the intervention if implemented more widely could include lack of engagement either by individual GPs or practices as a whole. Difficulties in getting all GPs together for practice visits could impact on the effectiveness of the intervention. Flexibility and tailoring intervention visits to GP availability would help address this potential problem.

If participating practices failed to engage, lack of commitment to prescribing change and ultimately wasted MMF resources could occur. Lack of practice engagement may require intervention from the MMF lead and if necessary, GP leads within the PCO to persuade GP colleagues of the benefits of the approach.

7.10 Policy Implications

Following completion of this study, significant restructuring of the NHS has occurred. PCTs have been abolished and the majority of commissioning functions are being delivered through commissioning consortia or Clinical Commissioning Groups (CCGs). During transfer of responsibilities from PCTs, medicines management functions were required to be actively integrated into existing or new commissioning organisations.[126] The NHS was expected to make the safe, legal and effective use of medicines a priority and ensure that evidence-based approaches to safe and effective use of medicines were not lost but strengthened.[126]

Commissioning consortia are advised that medicines management is not just about controlling prescribing costs but about realising the full benefits that optimal medicines use can deliver for patients and the NHS.[127] CCGs are required to fulfil a set of organisational medicines management competencies and must have medicines management expertise to optimise medicines usage and improve patient outcomes in all the services that they commission on behalf of their patients.[127]

CCGs should recruit and retain individuals with the appropriate skill mix and competencies. This includes individuals with the necessary skills to access and utilise quality summaries of evidence and who know how to interpret and where appropriate challenge, the evidence base underpinning the use of medicines.[127] Several Key Medicines Management Functions expected of CCGs based on principles consistent with the intervention approach are summarised in Table 7.8.

Key Medicines Management Functions	
Strategic Direction	• Ensure that evidence informed decision-making underpins the development of locally approved guidelines and commissioning agreements on the use of medicines • Ensure that individuals and teams have the appropriate education, training and developments necessary to ensure the safe, legal and effective use of medicines • Ensuring effective practice in the use of medicines in and across pathways and across a health economy including ○ development of joint robust processes and policies to support local decision-making about medicines e.g. horizon-scanning, evidence/appraisals
Professional Leadership	• Provision of advice on medicines and medicines related issues to the organisation and externally.
Workforce Development	• Ensuring that local healthcare teams have appropriate skills through education, training and development including GPs, nurses, practice pharmacists, practice support staff and others.
Medicines Expertise	• Has the skills necessary to access and utilise quality summaries of evidence • Knows how to interpret and where appropriate challenge, the evidence base underpinning the use of medicines. • Recruits, retains, or accesses the appropriate skill mix which takes account of emerging roles and organisations.

Table 7.8 Medicines Management Competencies Expected of Commissioning Consortia

Despite DoH policies and priorities intended to improve patient care, and requirements that comprehensive medicines management services are embedded within the new commissioning organisations, evolution of the revised NHS structure within the PCO has resulted in significant reduction in pharmacist skills base. Reduction in staffing levels to approximately 35% of previous capacity suggests that commissioning and funding of MMT services might not be a priority function for the new organisation as strategies intended to reduce staff costs were implemented.

Government commitment to utilise pharmacist skills in primary care more effectively and acknowledgement that prescribing advisers are increasingly active in promoting cost effective use of medicines may not necessarily have been considered within the emerging organisation. Local policy indicates a trend towards the dismantling of the established Medicines Management service, albeit one which has not traditionally focussed on influencing prescribing behaviour as implemented through the intervention model. This approach is inconsistent with study findings which have demonstrated the impact of skilled pharmacists on GP prescribing decision-making and the promotion of evidence-based practice through the intervention model.

Evidence-based prescribing is an essential component of good quality, effective and safe healthcare for patients which underpins national healthcare policy.[1,2,3] Many primary care pharmacists are highly skilled professionals possessing significant expertise in managing medicines.[9] They are also arguably the only qualified healthcare professionals equipped to support delivery of this agenda within the NHS.[11] It is suggested that a more appropriate and effective approach to supporting safe, effective and cost-effective prescribing and which would also support CCG and national policy objectives would involve adoption and implementation of the intervention.

The intervention is regarded as a 'package' or programme of support provided from within the Medicines Management function aimed at improving prescribing practice by facilitation of evidence-based prescribing.

Any such programme would need to sustainable and cost-effective and be part of a more comprehensive MMT strategy. However, based on study results it is believed that provision of such a service would improve prescribing practice, making it both evidence-based and more cost-effective. It is also believed that such a service supported with appropriate resources would also improve engagement with MMT and persuade GPs to prescribe more effectively and safely to the benefit of patients. A more comprehensive service would however need to be costed, marketed and fronted by a senior person with relevant knowledge and skills. If adopted more widely, the intervention would need to be appropriately monitored and evaluated.

Implementation of the intervention in the organisation is perceived as just one aspect of a formal structured Medicines Management function. As part of a wider and more comprehensive approach to promoting evidence-based prescribing, it would also be appropriate to identify and map out barriers to implementation of EBM in prescribing practice at micro, meso, and macro level. Possible solutions to overcome identified barriers could then be explored, and where feasible considered further to promote uptake of evidence in practice.

Promotion and adoption of evidence-based prescribing according to the model should support best quality patient-centred prescribing decision-making to the ultimate benefit of patients, healthcare professionals and the organisation as a

whole and in line with national health policies to promote safer and more effective prescribing.

7.11 Recommendations

Questions have arisen from this study regarding the role and functions of MMT within the organisation and GPs perceptions of it. Therefore several recommendations are specifically aimed at improving provision of prescribing support to GPs within the organisation where the study was conducted. It is believed that GPs would become better engaged with MMT and more involved in achieving clear and agreed prescribing objectives across the PCO.

- Reformat and restructure annual prescribing meetings to the intervention model. Where necessary, and if funds allow, schedule more frequent meetings.
- Discuss and agree annual prescribing objectives with GPs. Tailor to individual practices rather than implement generic audits which do not necessarily reflect true prescribing activities.
- Realign MMT data management resources to prepare relevant prescribing data including prescribing trends to support achievement of individual practice prescribing objectives and to inform intervention-type visits.
- Allocate a suitably qualified pharmacist to each practice to support GPs in achieving relevant and evidence-based prescribing objectives.
- Develop a GP Prescribing Lead Job Description and Role Specification to formalise and clarify the function and improve understanding of GP Prescribing Lead and MMT responsibilities.

Expansion of the intervention and wider implementation could significantly influence prescribing behaviour across the whole organisation.

- Offer the intervention to all practices within the PCO.
- Develop the intervention to cover other therapeutic areas within the BNF.
- Tailor practice visits and prescribing adviser input to individual practice needs.

Several additional activities were identified which, resources permitting might provide more comprehensive support in addressing GP prescribing information needs.

- Implement formal mechanism to raise GP awareness of new evidence/evidence-based guidance when available.
- Provide regular easily-digested pre-appraised evidence summaries/updates of evidence to help GPs keep up-to-date and overcome barriers in accessing evidence.
- Disseminate list of trusted evidence-based website resources to guide GPs to appropriate sources of prescribing-related information.
- Develop an educational role within the Medicines Management function to address GP lack of knowledge and awareness underpinning prescribing recommendations.

7.11.1 Areas for Future Research

- Conduct an economic analysis of proposed future service based on implementation of the intervention model.
- Identify and map out barriers to implementation of EBM in prescribing at micro, meso, and macro level.
- Conduct a study (preferably an RCT) with a larger sample size to further investigate the impact of the intervention and to contribute to the evidence base on translation of research findings into practice.

Chapter 8

Conclusions

The hypothesis that implementation of an intervention utilising a multifaceted approach, adopting strategies known to influence healthcare professional behaviour will affect GP prescribing behaviour according to the EBM paradigm is verified.

Recommendations to influence healthcare professional behaviours were addressed by utilising effective strategies to promote uptake of evidence (multifaceted approach, interactive educational meetings, audit, feedback, key messages summaries, clearly defined type of visitor and visit content) and by employing sustained efforts to improve prescribing behaviour.

The intervention tested constitutes a clearly defined, consistent and reproducible approach, (with component parts described) which was shown to be effective in promotion and implementation of evidence-based prescribing in practice. This study provides evidence to demonstrate that such an evidence-based approach when adopted is effective in influencing prescribing behaviour.

The study also demonstrated feasibility and delivery of the intervention in everyday practice and that the intervention can be delivered as intended and implemented more widely. Its impact on and acceptability to participants was also demonstrated.

Qualitative evaluation indicated that the intervention was successful in influencing the way GPs worked. GPs valued the intervention overall and many evidently developed as a result by becoming more reflective about their prescribing decisions and internalising key evidence-based prescribing messages.

The premise for this study was that there was very little evidence to demonstrate incorporation of evidence into the decision-making process and of its translation into routine practice, or that incorporation of evidence-based information into decisions improves patient care or patient outcomes. Not only has an effect on influencing uptake of evidence into prescribing decisions been confirmed, an effect on measurable patient-oriented outcomes has also been demonstrated. This finding addresses one of the key criticisms in that EBM lacks evidence to demonstrate its effect on patient-orientated outcomes.

Appendix 1

Literature Review - Methodology

Electronic database searches were conducted in EMBASE (Drugs and Pharmacology and other aspects of Human Medicine) and Medline (General Medical Database) using the National Electronic Library for Health (NeLH) database searching facility. (More recently accessible via the NICE website using the Healthcare Database Advanced Search).

The literature search question was structured according to the PICO Model whereby, the population of interest, the intervention of interest, comparator (if there is one) and the outcome are defined. The different components of the question were combined using Boolean Operators (AND and OR)

In this instance, the population of interest was GPs, the main intervention was centred on pharmacists using an academic detailing or educational outreach approach and the outcome was impact on prescribing. In this case, there was no specific comparator.

Search terms were derived from keywords indicated below, using truncation to refine textword searching. Search terms were also 'Mapped to Thesaurus' to access relevant subject headings. The search was based on key words or phrases appearing in Title or Abstracts. Limits were applied to published articles from '1988 to Current'

The literature search was structured as follows:

((GENERAL PRACTICE/) OR (("general practice" OR "family practice").ti,ab) OR (GENERAL PRACTITIONER/) OR (("general practitioner*" OR gp*).ti,ab) OR (("family physician*" OR "primary care physician*").ti,ab))
AND
(((PHARMACIST/) OR (pharmacist*.ti,ab) OR (("prescribing advis*" OR " pharmac* advis*").ti,ab))
AND
(((advice OR education* OR inform* OR feedback OR audit).ti,ab) OR ((intervention* OR meeting* OR visit* OR outreach OR detail*).ti,ab))
AND
((PRESCRIPTION/) OR ((prescrib* OR prescrip*).ti,ab)))
AND
(EBM OR EBP OR "Evidence-Base*" OR "evidence base*" OR evidence*).ti,ab [Limit to: Publication Year 1988-Current]

Abstracts of all publications identified in the searches were scanned for suitability and if relevant, full text articles were accessed.

NB: Broad (higher) searches were conducted to ensure that relevant articles were not missed. Abstracts identified from these searches were all scanned for suitability. The additional searches combining search terms relating to EBM were conducted to identify if there were any specific articles which incorporated interventions based on delivery of evidence based interventions. No articles with EBM as the basis of interventions to change behaviour were identified following review of abstracts.

Appendix 2

NICE Recommendations for Management of OA

- Exercise should be a core treatment for people with OA irrespective of age, comorbidity, pain severity or disability. Paracetamol and/or topical NSAIDs should be considered ahead of oral NSAIDs or COX-Inhibitors. (Ref NICE)

- NSAIDs or COX-2 Inhibitors should only be used when other safer treatments are ineffective or not tolerated and should be prescribed at the lowest effective dose for the shortest period of time owing to potential gastrointestinal, cardiorenal, and liver toxicity. (NICE, MeReC)

- Individual patient risk factors should be taken into account when prescribing NSAIDs.

- Where necessary, a proton pump inhibitor (PPI) should be offered for GI protection.

- Other drugs such as aspirin and SSRI antidepressants increase GI risk.

- NSAIDs should not be prescribed for patients with active peptic ulcer disease, past history of GI bleed, renal or heart failure. "At risk" groups also include those with established CVD disease, smokers, people with diabetes, and age > 65 years. (Ref CG 59)

NICE Recommendations for Management of RA

NICE Guidance recommends that patients are offered disease modifying anti-rheumatic drugs (DMARDs) as the mainstay of their management. (Ref CG 79)

- For symptom control, NICE recommends analgesics. If NSAIDs or COX-Inhibitors are offered, they should be prescribed with a PPI for gastro-protection.

- Because of potential gastrointestinal, liver and cardio-renal toxicities individual patient risk factors including age and individual patient risk factors should be taken into account. (Ref CG 79).

Appendix 3

Therapeutic Topics for EBM Prescribing Intervention - Key Messages, Outcomes and Data Source
An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

BNF Chapter	Topic	Key Messages / Rationale	Outcome - ePACT	Outcome - Clinical	Data sources / Evaluation

Cardiovascular/ Endocrine	• Type 2 diabetes
	• Oral Hypoglycaemic agents
	  • Glitazones
	  • Metformin
	  • Newer Drugs
	
	• Management of cardiovascular risk in T2DM Hypertension, lipids.
	• UKPDS
		Appropriate use of medication in T2DM
		
		• Safety and efficacy issues around glitazones, in particular rosiglitazone
		• Importance of use of metformin to reduce cardiovascular events
		
		Importance of managing cardiovascular risk, specifically hypertension in patients with T2DM
			Primary outcome
			• Increase in prescribing of metformin
			
			Secondary outcomes
			• Reduction in prescribing of Glitazones
			• Overall reduction in prescribing of newer drugs
				Secondary outcome
				Proportion of T2DM patients achieving target
				• HbA1c 7.5%, 9.0%
				• BP
				• Total cholesterol
				at end of study period compared with pre-intervention.
				
				Renal targets
				• Increase in prescribing of ACE-I/A-II-As for T2DM patients with m/a
				• Proportion of T2DM patients achieving BP <140/80mmHg
				• Proportion of T2DM patients with m/a achieving BP <130/80mmHg
					• ePACT
					ADQ / ASTRO PU for quarter immediately before intervention and final quarter of intervention.
					
					• Clinical
					Data from practice system
					
					• Clinical
					Data from practice system

BNF Chapter	Topic	Key Messages / Rationale	Outcome - ePACT	Outcome - Clinical	Data sources / Evaluation
Musculoskeletal	NSAIDs	Safety issues relating to use of NSAIDS Safety issues relating to Diclofenac Safety issues relating to Coxibs	Primary outcome • Reduction in prescribing of diclofenac Secondary outcomes • Reduction in overall prescribing of NSAIDs (including COX-II Inhibitors) • Relative increase in prescribing rates of ibuprofen and naproxen compared with diclofenac	Secondary outcome • Reduction in proportion of elderly patients (>65) on NSAID repeats • Proportion of patients with risk factors on NSAIDs	• ePACT Data ADQ / ASTRO PU for quarter immediately before intervention and final quarter of intervention. • Clinical Data from practice system

Appendix 4

Pharmacist Details and Postgraduate Qualifications

Pharmacist ID	Post Graduate Qualifications *	Years Registered ** (Pharmaceutical Register)
Ph 1	• PG Diploma - Community Pharmacy	19
Ph 2	• PG Certificate – Clinical Pharmacy	23
Ph 3	• PG Diploma – Pharmacy Practice • M.Sc. - Safety and Quality, Healthcare • M.Ed.	15
Ph 4	• PG Diploma – Clinical	22
Ph 5	• M.Sc. – Pharmaceutical Sciences • Independent Prescriber	21

* Highest Level Post-Graduate Qualifications Achieved Indicated
** Years Qualified and Registered as a Pharmacist

Pharmacist PCT Roles included:

- Principal Pharmacist Clinical Services Lead (3)
- Specialist Pharmacist (Area Prescribing Committee and Formulary)
- Consultant Pharmacist (DoH Defined Role)

Appendix 5

NPC Training Lesson Plan Template

Session Plan for NPC Plus LTC Update

Lesson Plan	
Trainer	**
Date	
Session Title	NPC Plus Type 2 Diabetes and NSAIDs
No of Students	20
Time	10.00a.m. – 4.00p.m. Duration 6 hours
Session Title	
Aims of Session	• To review the key principles of NICE guidance on Type 2 diabetes and best practice around NSAIDs. • Using the principles of information mastery, review the key therapeutic principles of an evidence based approach in the management of Type 2 diabetes and use of NSAIDs. • To apply the evidence base through review of case studies.
Specific Learning Outcomes	• Describe the key principles of evidence based prescribing in the management of Type 2 diabetes including: o The benefits of tight blood pressure control vs tight blood glucose control o Management of cardiovascular risk o Management of blood glucose • Describe the key principles of evidence based prescribing of NSAIDs including: o The NICE guidance on the management of osteoarthritis o cardiovascular and gastrointestinal risk o the three steps to appropriate NSAID use • Apply the key therapeutics in the clinical management of patients • Identify priorities for implementation
Previous Knowledge Assumed	• Clinical background that enables basic understanding of key messages
Materials and Equipment Required	• Lesson plan and facilitators notes. internet access • Projector, laptop, slides and handouts • Register of students • Pens, markers • Flipchart, smiley facts • Toys, postcards
Assessment Method	Evaluation form Case Study worksheets Feedback

Appendix 5 (Cont)

Lesson Plan Template

Session Plan for NPC Plus LTC Update

Timing	Objectives / Learning Outcomes	Resources	Facilitator Activity	Student Activity	Assessment
10.00am Creating environment conducive to learning Icebreaker Introduction	• Introductions - Postcards • Aims and Objectives for day • Establish baseline knowledge • Highlight NPCi	Crib Sheets, pens Quiz on arrival Flip Chart – What want to get out of it	Welcome group (universal Truths & cover all bases) Set ground rules Introductions Use of NPC resources Discussion	Undertake quiz Individual feedback Group discussion	Evaluation feedback Acuity regarding atmosphere/ engagement Participation and Evaluation
10.15 - 11.15am	Benefits of tight blood pressure control vs tight glucose control	Case study sheet Flipchart Powerpoint slides - highlight evidence Internet access Smiley faces	Facilitate group task – using IM skills identify evidence base management of 'John' Powerpoint Flipcharts	Group discussion- Task use online resources to identify evidence base for management of 'John'	Group and individual participation Case study Evaluation
11.15 - 11.30am	BREAK				
11.30 - 12.30am	Management of cardiovascular risk Management of blood glucose	Case study sheet Flipchart Powerpoint slides - highlight evidence	Facilitate group task – using IM skills identify evidence base management of 'John'	Group discussion- Task use online resources to identify evidence base for management of 'John'	Group and individual participation Case study Evaluation
12.30 - 1.00pm	Action planning	Detail Aid Matrix	Facilitate group discussion	**Planning Matrix** Aim of session Areas of controversy Mandatory literature reading Possible starters for 10 Questions for closure Materials to take with you **Selling messages to colleagues & patients** Key Message Feature Benefits Credibility	Group and Individual participation and Evaluation
1.00pm	LUNCH				

Timing	Objectives / Learning Outcomes	Resources	Facilitator Activity	Student Activity	Assessment
1.30 – 1.45pm **1.45 – 2.15pm**	Intro – What are NSAIDS used for? How can we measure musculoskeletal pain? Key recommendations in NICE OA guideline: Outcomes Non-pharma treatments- Exercise Topicals – short bursts Paracetamol – good for mild to moderate Opioids – lack of benefit (placebo trials)	Powerpoint Flipchart Powerpoint slides to highlight evidence for each	Powerpoint slides, facilitate feedback on flipchart Write on flipcharts and facilitate discussion	Group discussion Group to flipchart key NICE recommendations Group discussion	Group and Individual participation and Evaluation Group and Individual participation and Evaluation
2.15-2.30pm Case Study **2.15-2.30pm GI Risks** **2.30-2.45pm CV risks**	NSAID Risks Diclofenac- Highlight increased risks Ibuprofen/aspirin – is there a problem? Heart failure – increased risk if predisposition	Case Study	Powerpoint to highlight evidence and facilitate discussion	Groupwork – Case study To feedback and highlight key points	Group assessment using case study - Individual participation
2.45pm	BREAK				
3.00 – 3.45pm Action Planning	Implications for practice – Summary	Tool 5 Action Plans	Set task – groups to identify priority groups fir implementing change	Groupwork – Must , should, could action planning	Action plans
3.45pm Revisit Agenda	Reinforcing the learning and confirming covered learning needs	Flipchart	Facilitate discussion and feedback	Groupwork	Assessment, participation and evaluation
3.55pm Evaluation	Reinforce learning – identify key learning points for implementation	Juggling ball	Facilitate group feedback and ask individual one thing they are going to do next week	Individual feedback – one thing they will do differently as a result of the workshop	Post workshop feedback
Learning Styles met in this session					
Visual Powerpoint slides Flipchart exercises	**Audio** Group discussion exercises – Case studies Facilitator discusssion	**Read/Write** Case studies Group discussion exercises Action Planning Evaluation		**Kinaesthetic** UTCAB Evaluation Juggling ball	

Appendix 6

NPC Pharmacist Training

Aims, Learning Objectives and Expected Outcomes

Information Mastery

The aims of the session were:

- To review an evidence based approach to clinical practice and decision making
- Understanding of common terms and techniques used in published research
- Asking of relevant questions when presented with published research - especially in relation to new medicines
- Raise awareness of skills required to interpret absolute benefits from data, and use summaries of evidence in decision making
- Accessing useful and easily available evidence when faced with an information need.
- Communicating the evidence.

Therapeutics Update - T2DM

The Aims of the session were:

- To review the key principles of NICE guidance on Type 2 diabetes and best practice in management of Type 2 diabetes
- Using the principles of information mastery, review the key therapeutic principles of an evidence based approach in the management of Type 2 diabetes
- To apply the evidence base through review of case studies.

Specific Learning Outcomes:

- Describe the key principles of evidence base prescribing in the management of Type 2 Diabetes including:
    - The benefits of tight blood pressure control vs tight blood glucose control
    - Management of cardiovascular risk
    - Management of blood glucose
- Apply the key therapeutic principles in the clinical management of patients
- Identify priorities for implementation

Appendix 6 (Cont.)

NPC Pharmacist Training

Aims, Learning Objectives and Expected Outcomes

Therapeutics Update - NSAIDs

The Aims of the session were:

- To review the key principles of NICE guidance and best practice around use of NSAIDs
- Using the principles of information mastery, review the key therapeutic principles of an evidence based approach in the management of Type 2 Diabetes and use of NSAIDs
- To apply the evidence base through review of case studies.

Specific Learning Outcomes:

- Describe the key principles of evidence based prescribing of NSAIDs including:
    - The NICE guidance on the management of osteoarthritis
    - Patient risk factors and the use of NSAIDs
    - Evidence relating to cardiovascular and gastrointestinal risk
    - The three steps to appropriate NSAID use
- Apply the key therapeutic principles in the clinical management of patients
- Identify priorities for implementation

Therapeutics Update – RAS Drugs

Key Aims of the session were:

- To review factors guiding choice of RAS drug (efficacy, safety, patient factors, cost)
- Evidence based practice – Review evidence for recommended ACE-I first line
- Evidence based practice – Review evidence for recommendation for appropriate use of A-II-As if ACE-I discontinued
- Therapeutic dilemmas (1) Combination Therapy
  Therapeutic dilemmas (2):
    - Recommendations for RAS drugs in pregnancy/breast feeding?
    - Risk of MI with A-II-As?
    - Place in therapy of new direct renin inhibitor, aliskiren?
- Local prescribing patterns. How are we doing? How can we improve?

Appendix 7

Academic Detail Training

Key Aims of the training - To cover:

- An overview of what works in effective communication and influencing effectively.
- How to deliver a consistent, clear and compelling message.
- Principles of effective face to face and group communication
- "Detailing skills"
    - Questioning techniques
    - Identifying needs
    - Summarising techniques
    - Gaining agreement
    - Action planning
- Development of detail aids and delivery of key messages
- Breaking down the communication/detailing task into manageable chunks
- Influencing Skills
    - Influencing Behaviour
- Presentation skills
- Use of visual aids
- Pre detailing activities:
    - Choosing what messages to use, with whom and when
    - Defining objectives
- How to follow up and reinforce face to face communication
- Embedding and applying the training
- Measuring progress
- Opportunity to implement and practice techniques

Specific Learning Outcomes:

For each participant:

- Gaining an understanding of communication styles,
- Confident use of the detailing structure (story board),
- Skilled use of questioning techniques.
- Ability to manage and handle clinician raised objections.
- Ability to draw the detail to a close with an agreed "call to action" by the clinician.
- Structuring a discussion and presenting reference material.
- Provision of an effective framework for group presentation - delivering effective presentations, tackling objections, challenging current practice, and group discussion management.

Appendix 8

Academic Detailing - Training Approach

The detailing methodology, adapted to the project, focussed on the principles and processes to enable clear and compelling communication within the professional setting.

Aim: To reflect the approach known to be successful within the pharmaceutical sector by adopting structured methodologies and which were anticipated to be most effective when all aspects are addressed.

- Identification and targeting (segmentation) of the detail audience
- Preparation of the detailing message
- Support materials (detailing aids, slide presentations, reference material etc.)
- Skill learning for those undertaking the “Academic detailing”
- Follow-up and assessment of success

The course was structured to develop detailing skills for application in both one-to-one and group meeting situations.

Detailing Skills

Principles of Academic Detailing Approach:

- Focused, directed discussions which follow a planned approach (as determined in the detail planning matrix).
- Identification of needs and issues of the participants and presentation of cohesive arguments backed up by referenced facts.
- The conclusion of the detail is to agree a “call to action”. i.e. to agree that the clinician take a course of action.
- The agreed course of action may then be followed up and confirmation of the action having been completed will form the start of the next “detailing” visit.

The training therefore focussed on development of the pharmacists skills to achieve the predetermined objectives within the practice visits.

Appendix 8 (Cont.)

Pre-Course Preparation and Learning

Context:

Pharmacist participation in pre-workshop training in order to consider the objectives and desired outcomes of the intervention and to start to structure their thinking and approach to delivering the intervention utilising detailing techniques.

Format:

- Two pre-workshop group sessions involving all pharmacists involved in delivering the intervention.
- Teleconference discussion with the trainers in the form of a structured workbook and with access to the training materials via desktop computer.

Aims:

- To provide an introduction to the process and principals of academic detailing defining its context and rationale.

Content:

- Principles of communication
- Technique of developing an influential detail and detail structure.
- Participants introduced to the concepts of an adoption ladder, a tool which may be used in communication and driving change in behaviour and which assists the person conducting the presentation to structure detailing tasks and measure progress towards their desired outcome.
- Participants introduced to the concept of a questions / issue bank which may be used to anticipate and identify four categories of questions or opinion which may constitute diversion by the meeting participants and in order to be able to challenge such diversion or objection
- In between the two sessions, the pharmacists worked together on development of a written adoption ladder and suggested question bank, based on their experiences of working with GPs in practices. These were reviewed in the second session.

Learning Outcomes:

At the end of the sessions the participants should be prepared in advance of the main training with:

- An understanding of the detail communication process and structure
- An adoption ladder
- An objection/ question bank
- Knowledge of the four categories of diversion, and how to handle them

Appendix 9

NHS Cambridgeshire

Evidence Based Prescribing Support from Primary Care Prescribing Advisers Academic Detailing – Review Session

Date: 24th August 2010
Time: 1.00 - 5.00pm
Venue: PHN Conference Room, Hunts Area Office

A G E N D A

1.	Introduction - Study Aims and Objectives - Detail Aids, Data	MW
2.	Academic Detailing	MW
3.	Review - Change Theory - Openings - Questions and Listening - Obstacles ans Obstructions - Getting Agreements - Record Keeping / Reflection	TY / MW
4.	Summary	MW / TY

Circulation:

Pharmacists
Facilitator

Appendix 9 (Cont.)

Summary of Academic Detailing Review Session

We reviewed techniques used in 'academic detailing' also known as 'educational outreach'. This involved exploring the needs and wants of the clinicians involved.

As we have discussed previously, the principles of educational outreach are based on the following:

1. Investigate baseline knowledge
2. Focus on specific categories of prescribers
3. Define clear educational and behavioural objectives
4. Establish trust and credibility
5. Encourage doctor/prescriber participation
6. Provide concise graphic materials
7. Highlight and repeat key messages
8. Reinforce with follow up visits

Essential elements - Keep to time…..ensure it's well targeted
Practice; practice; practice ……

Application of the approach is also summarised in slides in the presentation

- Preparation
  - Key Messages
  - Features
  - Benefits
  - Trust / Credibility
  - Suitable Questions

- The visit
  - Aim of session
  - Areas of controversy
  - Mandatory literature
  - Possible 'Starters for 10'
  - Questions to ascertain closure
  - Materials to take with you

As discussed, the Planning Matrix for NSAIDs and T2DM should provide the information you need based on the above headings. These have been forwarded already and any revised versions will be forwarded to you when and if updated. Copies will also be in your individual folders with information on the outcomes being measured and a copy of the brief presentation.

Important: Copies of the attached (NAO) document have been provided to you all previously. Please read Chapter 1, ie the Introduction (Pages 6,7) *and* Chapters 6 and 7 before you go on the visits. This should help put the visit (and the project) in context and why the approach using detail aids, prescribing data and our own expertise and clinical knowledge etc. is adopted. It clearly identifies the principles which we have covered in the training but not at the exclusion of other aspects of the package.
The above report can be accessed using the following link:
http://www.nao.org.uk/publications/0607/prescribing_costs_in_primary_c.aspx
If you have any questions or require further clarification, please do not hesitate to ask.

Appendix 9 (Cont.)

Academic Detailing Review Session

Presentation

Academic Detailing

Melanie Whittick

Aim

To have a basic understanding of Academic Detailing and its practical application.

Social Marketing

The 'selling' of ideas as opposed to physical products to achieve health and social solutions

Kotler P, Roberto E, Social Marketing. Strategies for changing public behaviour. New York: Free Press 1989

Some key ideas/terms approaches

- 'push' or 'pull'
  - You can only push the change principles
  - Sell the benefits of the change
  - You want people to pull the idea towards themselves
  - People need to adopt the idea themselves so that they have ownership

For more information see NPCi Improvement Skills and Tools – spread and sustainability http://www.npci.org.uk/lift/lift.php

Academic Detailing

The delivery of educational messages about how to achieve better health outcomes in the patient's interest

- One to one communication
- Uses the principles of Social Marketing
- Not driven by commercial interest
- Focused on achieving behavioural change
- Delivered in the prescriber's own time and practice area

Academic Detailing is . . .

Using 'selling' to implement ideas, new knowledge and concepts

Evidence base?

'An evidence base exists supporting the impact of academic detailing on behavioural change, particularly prescribing behaviour'.

Principles of Academic Detailing

1. Investigate baseline knowledge
2. Focus on specific categories of prescribers
3. Define clear educational and behavioural objectives
4. Establish trust and credibility
5. Encourage doctor/prescriber participation
6. Provide concise graphic materials
7. Highlight and repeat key messages
8. Reinforce with follow up visits

Essential elements
Keep to time…..ensure it's well targeted

Practice; practice; practice ……

The Package

- Academic detailing - Preparation
  - Key Messages
  - Features
  - Benefits
  - Trust / Credibility
  - Suitable Questions

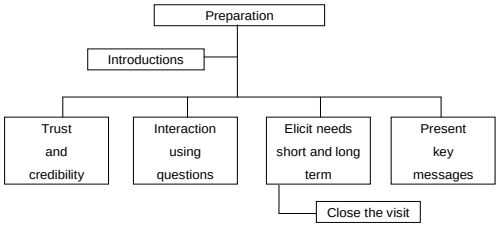
The Package

- Academic detailing - The visit
  - Aim of session
  - Areas of controversy
  - Mandatory literature
  - Possible 'Starters for 10'
  - Questions to ascertain closure
  - Materials to take with you

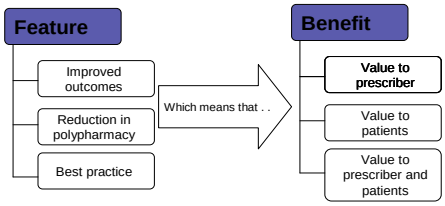
Distil the aim into key messages

- Choose 4/5 key messages
- Repeat throughout the session
- Use adult learning theory – i.e. account for different learning styles
- Address deep learning and surface learning

The Structure of the Visit



Present features as benefits of the key messages



Group feedback?

- Summary
- Potential benefits / pitfalls?
- Next steps?

Academic Detailing 'techniques have been shown to reduce inappropriate prescribing as well as unnecessary health care expenditures'.

Soumerai S, B and Avorn J (1990) Principles of Educational Outreach ('Academic Detailing') to improve clinical decision making. Journal of the American medical Association Vol.263 No. 4 549-556

Appendix 10

Key Messages in Development of Detail Aids - NSAIDs

Therapeutic Topic – NSAIDs and Musculoskeletal Pain
Key Messages for Pharmacists Delivering the Intervention

Non-steroidal anti-inflammatory drugs (NSAIDs) including COX-Inhibitors carry the risk of side effects, which can be serious and life-threatening. Important side effects include gastrointestinal (GI) complications (e.g. perforation, ulcer, bleeding) and cardiovascular (CV) (e.g. stroke, myocardial infarction).

- COX-II inhibitors and NSAIDs have similar analgesic effects and do not differ in efficacy for pain relief.
- The level of risk varies between individual NSAIDs
- COX-II inhibitors have reduced risk of causing GI ulcers than older NSAIDs, however, they increase cardiovascular risk
- Diclofenac is associated with a similar cardiovascular risk as COX-II inhibitors

NICE Guidance on management of osteoarthritis – largely supports the evidence base.

- Exercise should be a core treatment for people with OA irrespective of age, comorbidity, pain severity or disability.
- Healthcare professionals (HCPs) should consider offering paracetamol for pain relief
- Healthcare professionals (HCPs) should consider offering *topical* NSAIDs for pain relief.
- **Paracetamol and/or topical NSAIDs should be considered ahead of oral NSAIDs, COX-Inhibitors or opioids**
- It is particularly important to use NSAIDs or COX-II inhibitors **only** when other safer treatments are ineffective or not tolerated
- When offering treatment with an NSAID or COX-II inhibitor, these should be prescribed with a PPI choosing one with the lowest acquisition cost.
- Prescribe at lowest effective dose for shortest possible period of time
- Owing to potential GI, cardio-renal and liver toxicity
    - Take into account individual risk factors including age when choosing NSAID/COX-II and dose to be prescribed
    - Assess/monitor patient risk factors
    - Consider alternative analgesic if patient already taking low-dose aspirin

What does the evidence say?

Cardiovascular risk

- Although risk to individual patient is small, CV risks are important a population level because of the volumes in which they are prescribed.
- Estimated risk
    - Coxibs account for approximately 6% items in England. – potentially responsible for 240 additional/premature CV events per year
    - Diclofenac accounted for 46% NSAID prescriptions (2007/2008) – potentially equating to 2000 additional/premature CV events per year
- Coxibs (celecoxib, etoricoxib▼), are associated with a small excess risk of thrombotic events compared with no treatment (about three per 1000 users treated for one year).

- Two coxibs have already been withdrawn from worldwide markets because of unacceptable risks (rofecoxib, lumaricoxib).
- All coxibs are contraindicated in patients with established CV disease (IHD, PVD, CVD).
- Coxibs have a higher CV risk than ibuprofen ≤1200mg per day or naproxen 1000mg.
- Traditional NSAIDs may be associated with an increased risk of thrombotic events. Diclofenac 150mg/day appears to be associated with a similar excess risk to that of coxibs.
- Low-dose ibuprofen (≤1200mg/day) and naproxen 1000mg/day do not carry the same CV risks and should be first line choice for most patients (taking into account GI risks and interpatient variability in response)
- The evidence suggests that there is no safe period over which there is no risk of events. Risk increases with dose and persists throughout treatment.
- Cardio-renal effects are not affected by COX-selectivity and contribute to CV risk. (Heart failure, oedema, hypertension).

GI Risk

- GI risk increases with age of patient, co-morbidities (including cardiovascular disease, diabetes, smokers)
- Coxibs, are associated with a lower GI risk than traditional NSAIDs. However, their GI-safety advantage is diminished when co-administered with aspirin.
- Of the traditional NSAIDS, low-dose ibuprofen is associated with a lower GI risk than diclofenac and naproxen.
- Use of a proton pump inhibitor (PPI) with any NSAID reduces the risk of GI side effects.
- Benefits from gastroprotection largely depend on the individual patient's baseline risk of GI complications.
- There is, as yet, no good evidence that adding a PPI to a coxib is more beneficial, equivalent or a worse option than adding a PPI to a traditional NSAID.
- There is an increased GI risk with co-prescription of aspirin.

What does this mean in practice?

- Prescribing of NSAIDs should be based on the safety profiles of individual NSAIDs and on individual patient risk factors.
- NSAIDs should be used at the lowest effective dose and for the shortest period of time necessary to control symptoms.
- Low-dose ibuprofen (≤1200mg per day) is an appropriate first choice NSAID in view of its low risk of GI and CV side effects.
- Low-dose ibuprofen or naproxen 1000mg would appear more appropriate than other NSAIDs for patients in whom CV risk is a significant consideration in decision making.
- Consider prescribing a PPI with any NSAID to reduce the risk of adverse GI effects, particularly in those who are at high GI risk (includes anybody aged 65 years or older) and long-term NSAID users.
- Although coxibs are associated with a lower risk of GI side effects than traditional NSAIDs, there is no good evidence to support the use of coxibs alone ahead of traditional NSAIDs co-prescribed with a PPI.
- Medication reviews of NSAIDs should consider:
    - Whether the NSAID is necessary
    - When reviewing the treatment of patients receiving diclofenac, some cases it may be appropriate to consider alternatives(especially in patients with significant risk factors for CV disease):

- Patients who change from diclofenac 150mg/day to 1200mg ibuprofen/day would probably reduce both GI and CV thrombotic risk.
  Patients who change from diclofenac 150mg/day to naproxen 1000mg/day would reduce their CV thrombotic risk, but may slightly increase their risk of GI complications. However, if PPI is introduced, the GI risks may also be reduced.

NSAID Initiation – Points for consideration

Is the NSAID needed?

- Is paracetamol an appropriate first line analgesic choice?
- What about topical NSAIDs first line / in combination with paracetamol?
- Is the NSAID prescribed appropriate based on the patients CV risk?
- Is the NSAID prescribed the one with the lowest GI risk suitable for that patient?
- Should a PPI be co-prescribed to reduce the risk of adverse GI effects? (high risk)
- When should treatment / dose next be reviewed?
- Consider NSAID switch to lower risk choice
- Remove from repeat

Points for Good Practice / Audit

- Is the indication for NSAID recorded
- No prescribing for patients with
  - Active PUD
  - Past history of GI bleed
  - Renal or heart failure
- "At risk" groups should have risk assessment documented
- Review to address continued need and whether still appropriate
- Who should be prioritised for review?
  - Those with established CVD risk
    - On aspirin
    - Smokers
    - People with diabetes
  - Those at high GI risk
    - Age >65 years
    - History of GI bleeding
    - On medicine which increase risk of GI bleed warfarin, aspirin, corticosteroids
    - Serious co-morbidity eg CV, renal hepatic, diabetes, hypertension
    - Prolonged use or high doses of NSAIDs
    - Excessive alcohol
    - Heavy smokers

What is the evidence for other medications?

- Both paracetamol and NSAIDs (including coxibs) have a small to moderate effect in reducing pain. (Cochrane, 2006).
- Evidence for the use of glucosamine and chondroitin is not robust
- Tramadol. Tramadol is no more effective than other weak opioid analgesics and its safety profile is problematic. (Cochrane, 2006, CSM, 2006)

Appendix 10 (Cont.)

Key Messages in Development of Detail Aids - T2DM

Therapeutic Topic – Management of Type 2 Diabetes (T2DM)
Key Messages for Pharmacists Delivering the Intervention

T2DM is a long term conditions associated with increasing obesity and an aging population. Although characterised by raised blood glucose, it is essentially a cardiovascular disease associated with increased morbidity and mortality. People with T2DM are at almost twice the risk of dying from any cause than those without diabetes. There is evidence that effective management of the disease and associated risk factors increases quality of life and life expectancy.

- Lifestyle interventions are key in the prevention and treatment of type 2 diabetes. Dietary interventions and exercise aim to correct obesity, improve glycaemic control, blood pressure and blood lipid control.
- The single most effective intervention in those who smoke is smoking cessation.
- After stopping smoking, successful management of blood pressure is the most effective means of reducing cardiovascular risk in T2DM.
- Lipid management and use of aspirin are the next most effective interventions.
- Aims of treatment
    - Manage symptoms
    - Reduce life threatening or disabling complications (MI, stroke)
    - Manage renal disease, retinopathy and foot disease

UKPDS Study

Three main components

- **Blood glucose (BG)**
  Intensive BG control with sulphonylureas/insulin vs conventional BG control
- **Metformin**
  Intensive BG control with metformin (or SU/insulin) vs conventional control in obese/overweight patients
- **Blood Pressure (BP)**
  Tight BP control vs less tight BP control (ACE-I and ß-blocker comparisons)

Results

- Intensive BG control by either SUs or insulin decreased risk of microvascular problems but not macrovascular disease.
- Metformin reduced the risk for any diabetes related end-point (32%, p=0.002), diabetes related death(42%, p=0.021) and all cause mortality (36%, p=0.011) (Despite similar reductions in HbA1c for metformin compared with SUs/insulin) NNTs for aggregate endpoints and overall mortality were 10 and 14 respectively
- Risk reductions for tight BP control were 24% for any diabetes related end-points (p=0.0046), 32% for diabetes related death(p=0.019), 44% in strokes (p=01013) and 37% in microvascular endpoints (p=0.0092).

Conclusions

- Tight control of blood glucose
    - Important in terms of symptoms and microvascular complications
    - Benefit on microvascular problems not proven

- Metformin has an effect on macrovascular complications that is independent of its blood glucose lowering effect. Metformin is the hypoglycaemic drug of choice in T2DM
- Management of BP is as if not more important than tight control of BG

Questions
Does this support the high profile given the need for tight control of BG?
Think about the priorities for patients - The Diabetes Hand

Why are the following statements repeatedly quoted?
'Good glycaemic control significantly reduces risk of long term complications in T2DM'
'A 1% reduction in HbA1c reduces diabetes related deaths by 21%, risk of microvascular complications by 37% and risk of MI by 14%'

- All based on observational data from UKPDS 35 (Stratton et al and EPIC Norfolk)
- The papers generate a hypothesis based on epidemiological data.
- As yet there is no prospective RCT evidence to support this
- In fact, UKPDS results from SU/insulin arm refute this. Also Stettler meta-analysis

Conclusion: Managing BG is important but in isolation is not the key to reducing morbidity and mortality.

Blood Glucose

NICE Guidance
- Metformin first line choice oral hypoglycaemic agent (OHA) overweight and non-overweight
- SU second line or if metformin contraindicated
- Glitazones thirdline, dual therapy or triple therapy if HbA1c targets not reached

In practice
Metformin
- Importance of aiming to put all on metformin because of cardiovascular protective effects
- Step up dose gradually to reduce GI effects
- Use MR only after adequate trial of normal release (no evidence of beneficial effect of MR compared with NR

Glitazones
- Safety issues
- First drug in class, troglitazone was withdrawn (1997) after a few months because of hepatotoxicity.
- Both rosiglitazone and pioglitazone were introduced on the basis of their blood glucose lowering ability rather than ability to reduce complications of T2DM
- Only one published study specifically designed to evaluate secondary prevention of macrovascular events with a glitazone - PROactive Study. No significant difference in primary end-point. Statistically significant difference when analysis was restricted to the secondary endpoint. The number needed to treat was 48. NNH 63 for heart failure requiring hospitalisation.

- No definitive evidence that glitazones are associated with significant reduction in the long term microvascular or macrovascular complications of T2DM.
- Controversy regarding safety of glitazones, in particular rosiglitazone
- The evidence is now indicating that rosiglitazone is associated with cardiovascular morbidity and mortality. Conversely, pioglitazone appears to have better cardiovascular safety (excluding HF)
- Midlands Therapeutic Review and Advisory Committee reviewed the evidence for glitazones (April 2008). Concluded that Rosiglitazone cannot be recommended for prescribing based on current concerns about potential CV adverse effects and lack of evidence for improved patient-orientated outcomes and pioglitazone is suitable for use in primary care by a prescriber with a particular interest in T2DM. There is conflicting evidence regarding long term clinical benefits or harms on cardiovascular outcomes which dictates caution in its use.
- Fluid retention, heart failure are well known adverse events of glitazones. Effects on bone density and fracture risk and macular oedema are more recently reported concerns. The SPCs for both products now also carry warnings regarding all of these adverse effects.

Tight BG control

- Recently evidence from ACCORD and ADVANCE demonstrates that intensive BG lowering failed to show any reduction on cardiovascular events compared with standard treatment.
- Now concerns that that intensive BG control is actually harmful. ACCORD study (target HbA1c <6%, mean achieved target was 6.4%) was stopped early because of higher incidence in all-cause mortality in the intensive arm.

Self-monitoring of Blood Glucose

Two studies recently been published in the BMJ, ESMON and DiGEM trials. Both studies were funded independently without industry sponsorship.

- ESMON Study
  - No difference in HbA1c
  - Increase in depression and anxiety

- Economic Evaluation of DIGEM
  - Decreased QoL
  - Evaluation of cost in monitoring
  - Diabetes UK changed stance

Management of Hypertension –

Summarised in MeReC bulletin. Focussing on updated NICE Guidance

Drug Choice - Specified in algorithm

Step 1	<55 years		ACE-I
	>55 years or black		CCB or diuretic (D)
Step 2	A+C	or	A+D
Step 3	A+ C + D		
Step 4	Add in or consider specialist advice		

- In general however no compelling evidence of any clinically significant, drug specific effects to distinguish between drugs in terms of efficacy when BP lowering effect is taken into account.
- May be benefits for specific classes in specific patient groups

ALLHAT

- ALLHAT is one of the most important trials of hypertensive therapy.
- For primary end-points of fatal CHD or non-fatal MI there was no difference between chlorthalidone, amlodipine and lisinopril.
- There were some differences in secondary end-points. Amlodipine had a higher risk of heart failure and lisinopril had higher risk for combined CVD, stroke, heart failure and angina than chlorthalidone
- Diuretics are the preferred initial treatment for hypertension including in people with diabetes. Endorsed by JNC7.
- For patients with microalbuminuria initiate an ACE-I (A-II-A if intolerant)

CVD

- If CV risk low, assess using UKPDS risk engine. (NICE).
- Initiate simvastatin 40mg for most people aged 40 or over unless risk low (younger if CV risk high). Consider increasing dose to simvastatin 80mg unless TC less than 4mmol/l or LDL less than 2mmol/l. (NICE).
- For people with T2DM with established or newly diagnosed CV disease or raised ACR, initiate simvastatin 40mg. Consider changing statin or add ezetimibe (NICE).
- If either figure is below level, dose increase is not recommended
- NICE does not set lipid targets which patients are expected to achieve
- Single cholesterol levels may vary. HCPs should be aware of making treatment decision based on one reading
- The only published RCT of ezetimibe plus simvastatin did not produce beneficial effects compared with double placebo but raised safety concerns relating to cancer.
- Rosuvastatin. No reason to depart from recommendations.

Aspirin

- Use aspirin in higher risk patients and those aged 50 or older as long as BP is <145/90mmHg.
- Clopidogrel is alternative on those with clear aspirin intolerance
- POPADAD Trial. Study too small and underpowered to rule out benefit of aspirin in T2DM patients at risk of CV disease.

Appendix 11

Typical Evidence Based Resources Utilised in the Development of Detail Aids

Included the following (the list is not exhaustive):

NICE Guidance
Current NICE Guidance documents relating to T2DM and NSAIDs were key evidence based references utilised in the therapeutics training.

MeReC Publications
MeReC publications are high quality resources issued by NPC useful to a wide range of healthcare professionals. They provide concise pre-appraised evidence based information about medicines and prescribing related issues. Rapid Reviews are produced in response to requests for evaluation of key clinical trials or guidance as soon as they are published whereas MeReC bulletins focus on key therapeutic dilemmas – collating and summarising evidence and guidelines.
MeReC may produce drug specific and drug class focussed reviews as well as disease focussed reviews. The resources accessed provided and reinforced consistent key messages which are supported by high quality evidence based studies and other evidence based sources.

NPCi e-Learning
These resources are available for healthcare professionals through NPCi and are frequently used by primary care pharmacist prescribing advisers. A number of these are intended to be used as educational tools and may be used to promote behaviour change in prescribing.

- **'Key Slides'**

The 'Key Slides' are most akin to detail aids. They constitute are a limited set of slides summarising key messages relating to specific therapeutic topics. They are provided as PowerPoint presentations for discussions about the therapeutic topic. Key slides are accompanied by extensive notes for each slide, available as Word files and providing supporting evidence and discussion points. The slides and accompanying notes enable individuals to explain key messages and discuss important therapeutic issues with colleagues.

- **Data Focussed Commentaries**

Data focussed commentaries accompany the key slides. They consist of a short report comparing prescribing and other data with the evidence-base, highlighting areas where the evidence may not have been fully implemented. They also provide questions for reflection which may be useful for discussing current practice with colleagues.

Appendix 12

Study Detail Aids - NSAIDS

Musculoskeletal Pain

Non-steroidal Anti-inflammatory Drugs (NSAIDs)

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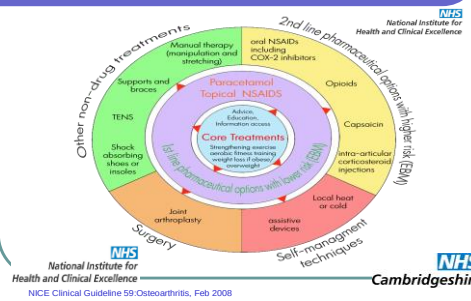
Targeting Treatment in OA



NHS National Institute for Health and Clinical Excellence

NICE Clinical Guideline 59:Osteoarthritis, Feb 2008

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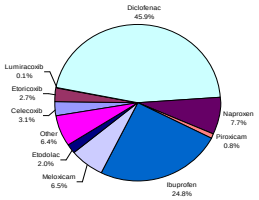
Background – *It's about Safety*

- All NSAIDs including Coxibs carry risk of side effects. Potentially serious and life threatening
  - GI (perforation, ulcer, bleeding)
  - CV (stroke, MI)
  - Renovascular (fluid retention, hypertension, HF)
- Need to review our NSAID prescribing to minimise risk to patients
- Thrombotic risk concern
  - 2 coxibs withdrawn because of unacceptable risk
  - Evidence suggests Coxibs and diclofenac have similar thrombotic risk
  - 3 additional events / 1000 patients / year

NHS Cambridgeshire

Risk / Prescription Volume Link

- COX-II inhibitors may cause 240 additional or premature CV events per year in England alone
- Diclofenac may cause 2000 additional or premature CV events per year



NSAID prescribing in England
April - June 2007: % total items (4.3 million)

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CV Risk - Overview

- Coxibs cause an increased risk of thrombotic events c.f. placebo (3 additional events / 1000 patients / year)
- Coxibs are contraindicated in patients with CV disease
- Risk increases with dose & persists throughout treatment
- Diclofenac 150mg/day has similar excess risk to coxibs
- Cardio renal effects apply to all NSAIDs including coxibs and contribute to CV risk
- Low dose ibuprofen (≤1200mg/day) and naproxen 1000mg/day have a lower thrombotic risk

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GI Risk - Overview

- All NSAIDs (including coxibs) carry a risk of GI side effects
- GI risk increases with age, co-morbidities (eg CV disease, diabetes, smoking)
- Concomitant aspirin greatly increases the GI risks of NSAIDs and reduces any GI safety advantages of coxibs
- Dyspepsia as common with coxibs as with traditional NSAIDs
- No good evidence that addition of PPI to coxib is more beneficial than adding PPI to traditional NSAID
- Low dose ibuprofen (≤1200mg/day) is associated with lower GI risk than diclofenac or naproxen
- Evidence suggests there is no safe period of 'no risk' Risk increases with dose and persists throughout treatment

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Appendix 12 (Cont.)

Assessing the Risk

High CV risk

- Established CV disease
- Taking CV medication (aspirin and clopidogrel)
- Older men
- Smokers
- Diabetics

High GI risk

- Age >65 years
- History of GI bleeding, ulcer or perforation
- Taking medicines that increase risk of upper-GI AEs (warfarin, aspirin and corticosteroids)
- Co-morbidity: CV disease, renal or hepatic impairment, diabetes or hypertension
- Prolonged duration or maximum doses of NSAID
- Excessive alcohol use
- Heavy smokers

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What does this mean in practice?

- Base prescribing on safety profiles of individual NSAIDs and on individual patient risk factors
- Consider Paracetamol and topical NSAIDs first line
- Use NSAIDs at the lowest effective dose and for shortest period of time
- Low dose ibuprofen is an appropriate first line choice as lower risk of GI and CV side effects
- Low dose ibuprofen or naproxen would appear appropriate for patients where CV risk is a consideration
- Consider PPI with NSAID especially in those at high GI risk (including >65, long term use)

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Best Practice for NSAID prescribing

Don't use NSAIDs unless you have to
- non-drug interventions should be considered in every case
- Consider topical NSAIDs ahead of oral NSAIDs for OA
- Paracetamol can be effective

If you have to use NSAIDs, use them wisely
- assess benefits and risks; consider CV, GI and renal issues
- Use a *safer* drug (ibuprofen, then naproxen)
- lowest effective dose for the shortest period

Gastroprotection for patients at high risk
- Options are PPIs, double-dose H2RAs, misoprostol
- Co-prescribe PPI with NSAID for OA

Medication reviews for all NSAID users
- are NSAIDs effective/needed?
- drug holiday?
- no repeat prescriptions without review

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Practice Audit for NSAIDs

- Identify patients with active NSAID Rx
- Identify patients with contraindications for NSAIDs
  - Active peptic ulceration
  - Previous GI bleed
  - Renal failure
  - Heart failure
- Identify patients with
- >65, IHD, CV disease, PVD, history of PUD

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Consider the following

- Is NSAID still necessary?
- Does the NSAID prescribed have the lowest CV risk?
- Does the NSAID prescribed have the lowest GI risk?
- Should PPI be co-prescribed?
- When should the patient be reviewed again?

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For patients on higher CV risk NSAIDs

Consider switching them to

- Paracetamol 4g / day
  - Reduces CV
  - Reduces GI risk
- Ibuprofen 1200mg / day
  - Reduces CV
  - Reduces GI risk (PPI reduces risk further)
- Naproxen 1g / day
  - Reduces CV risk
  - May increase GI risk (PPI may reduce risk)

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Appendix 12 (Cont)

Study Detail Aids – T2DM

Type 2 Diabetes

Approach to Management

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Burden of Type 2 Diabetes

- T2DM reduces life expectancy by about 7 – 10 years
- Macrovascular disease
  - causes > 70% of deaths (CHD, CVA, PVD)
- Microvascular disease causes disability and suffering
  - retinopathy, renal disease, neuropathy, feet
- Metabolic complications
- Potential huge economic burden of treatment in terms of
  - lost earnings
  - cost to NHS (estimated 10% NHS expenditure, 2008)

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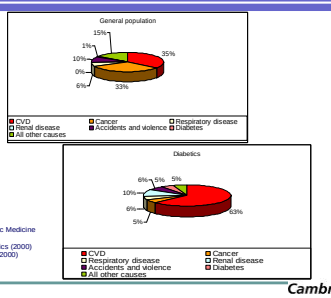
Death by Cause – T2DM



Laing et al (1999) Diabetic Medicine 16: 466 – 471
Office for National Statistics (2000)
General Register Office (2000)

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Death by Cause – T2DM (men)

	General population	Diabetics
CVD	35%	63%
Cancer	33%	5%
Respiratory disease	6%	6%
Renal disease	0%	10%
Accidents and violence	10%	6%
Diabetes	1%	5%
All other causes	15%	5%

Laing et al (1999) Diabetic Medicine; 16: 466 – 471
Office for National Statistics (2000)
General Register Office (2000)

Background – Key Issues

- Risk factors for T2DM - Cardiovascular
- Type 2 diabetes is essentially a cardiovascular disease associated with obesity and insulin resistance
  - Characterised by raised blood glucose
- How to prioritise treatment and target drug therapy
  - Evidence shows that more effective management of the disease and its associated risk factors increases quality of life and life expectancy
- Choice of medications to manage CV risk (BP, lipids) blood glucose and microvascular complications
- Role of old and newer drug therapies

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Evidence for Intervention

- UKPDS provides compelling evidence for approach to management
  - Recruited 5,102 newly diagnosed diabetics, (FBG > 6mmol/l)
  - Initially treated for 3 months with diet and advice
- Three main components:
  - **Blood glucose** - intensive BG vs conventional BG (+ insulin and sulphonylurea comparisons)
  - **Metformin** - intensive BG control in overweight patients metformin vs SU / insulin
  - **Blood pressure** - tight BP vs less tight control (+ ACE-I and ß-blocker comparisons)

UKPDS 33. Lancet 1998;352:837–853
UKPDS 34. Lancet 1998;352:854–865
UKPDS 38. BMJ 1998;317:703–713

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Appendix 12 (Cont)

What did UKPDS show us?

Take 100 people as in UKPDs - Over 10 years

- Intensive control of BG using sulphonylurea / insulin
  - Prevents about 3 people developing microvascular complications
    (mainly because they don't need retinal photocoagulation)
  - Do not prevent deaths, strokes or probably heart attacks
- Use metformin to control BG
  - Prevents about 7 heart attacks, 5 people from dying from diabetes complications and 8 from dying of any cause
- Intensive control of BP (over 8 years)
  - Prevents about 4 people having a stroke, 5 deaths from diabetes complications and about 5 from having microvascular problems

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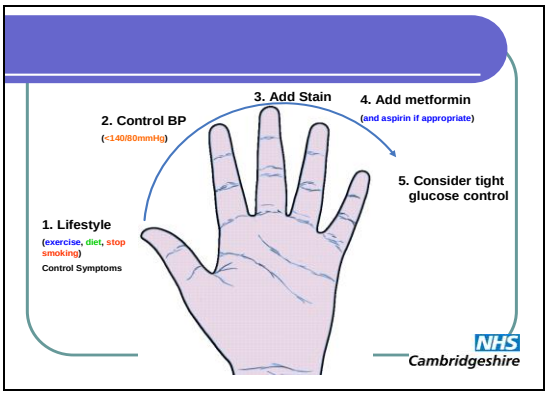

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1. Lifestyle Interventions

- Lifestyle interventions are key in prevention and treatment of Type 2 diabetes
- Diet and exercise to manage weight, correct obesity and to improve:
  - blood pressure, glycaemic control and blood lipids
- The most effective intervention to reduce CV risk in smokers is smoking cessation
- Structured education should be seen as an integral component of diabetes care
  - Health care professionals passing on the same messages repeatedly
- Management of depression

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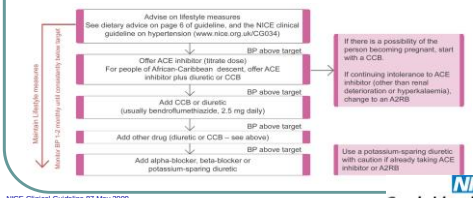
2. Control Blood Pressure

- Successful management of blood pressure is the most effective means of reducing cardiovascular risk (after smoking cessation). Which Antihypertensive?



NICE Clinical Guideline 87 May 2009

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3. Role of Statins in T2DM

- Next most effective intervention to reduce CV risk after control of blood pressure (and smoking cessation)
- Benefits approximately 20–30% relative risk reduction regardless of age, gender, lipid levels.
- Baseline risk is the key to the size of the absolute risk reduction
- Evidence is for simvastatin 40mg/day or atorvastatin 10mg/day
- Consider for all > 40 years and those <40 years with high CV risk
- Offer generic simvastatin
  - Local and national policy – simvastatin 40mg/day
- Assess lipids and modifiable risk factors 1-3 months after starting
- Titrate to simvastatin 80mg if
  - Cholesterol >4.0mmol/l
  - LDL >2mmol/l
- NB: Safety concerns with rosuvastatin (don't forget cerivastatin)

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4. Metformin / Aspirin

- Using metformin first line to control BG
  - Prevents about 7 heart attacks, 5 people from dying from diabetes complications and 8 from dying of any cause (UKPDS)
- Metformin has an effect in reducing cardiovascular risk which is independent from its glucose lowering ability
- *Intensive* control of blood glucose with SU / insulin does not demonstrate CV risk reduction shown by metformin
- Low dose aspirin
  - Evidence supports use in patients with high CV risk and those with existing CV disease (but control BP < 145/90mg)

1. UKPDS 34. Lancet 1998;352:854–865
2. POPADAD trial Belch J et al. BMJ 2008:337:a1840

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Appendix 12 (Cont)

5. Glucose Control

- Setting a target
  - Involve the patient in setting an individual HbA1c target
  - Avoid very intensive management
- Evidence from studies assessing intensive glucose lowering strategies ADVANCE, ACCORD, VADT
- First line metformin followed by sulphonylurea
- Self-monitoring of blood glucose
  - Only offer as integral part of self-management plan
  - Make available to those on insulin, on medication likely to cause hypoglycaemia and to monitor medication lifestyle changes and/or illness

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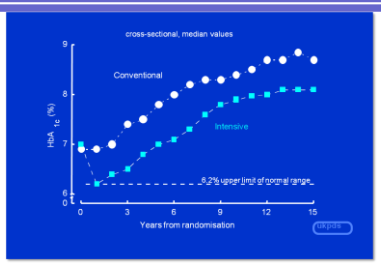
Glucose Control



HbA1c will rise over time whatever is done to control it

UKPDS 33. Lancet 1998;352:837–853

Summary

- Lifestyle modification is key to management - to be maintained
- Reducing cardiovascular risk is the main objective
  - Reducing BP is more important than worrying about drug choice
  - ACE-Is are acceptable first choice with thiazides good addition for most
  - Many will need combinations to achieve target
  - Avoid ARBs and doxazosin if possible
- Statins are appropriate for most patients
  - Simvastatin 40mg first line

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Summary (2)

- Is the emphasis on tight BG control justified by the evidence?
- Metformin for everyone with T2DM?
- Consider need for and frequency of self-monitoring BG Set realistic HbA1c target.
- Manage overall risk which is similar to that in patients with established CHD.
- Remember – Polypharmacy is the norm
  - Which drugs will you focus on if patients do not want to take all

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Appendix 13

Study Detail Aids – Supplementary Slides

Type 2 Diabetes

Approach to Management

Support Slides

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Aims of Treatment for Type 2 Diabetes

- Manage symptoms
- Reduce risk of major life-threatening or disabling complications (MI/stroke)
- Manage diabetic renal disease, retinopathy and foot disease

Note:

- Targets set by NICE can be demanding to reach
- Targets should be agreed with individuals as aggressive therapy of each aspect may not be appropriate for all.

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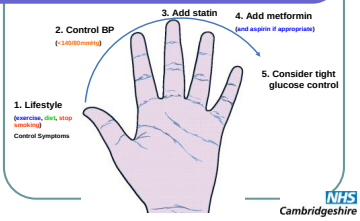
Summary



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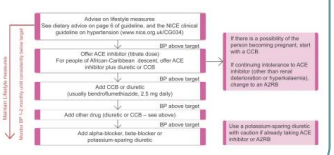
Algorithm for BP Control (1)



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Algorithm for BP Control (2)

Blood pressure management

Targets
- If kidney, eye or cerebrovascular damage, set a target < 130/80 mmHg.
- Others, set a target < 140mmHg.

If on antihypertensive therapy at diagnosis of diabetes
- Review BP control and medication use.
- Make changes only if BP is poorly controlled or current medications are inappropriate because of microvascular complications or metabolic problems.

If the person's BP reaches and consistently remains at the target
- Monitor every 4-6 months and check for possible adverse effects of antihypertensive therapy (including those from unnecessarily low blood pressure).

Measure BP annually if not hypertensive or with renal disease.
If BP > target, repeat measurement within:
- 1 month if > 150/90 mmHg
- 2 months if > 140/80 mmHg
- 3 months if > 130/80 mmHg and kidney, eye or cerebrovascular damage

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Anti-thrombotic therapy

Anti-thrombotic therapy

Age 50+ years and BP < 145/90 mmHG

Age < 50 years and significant other CV risk factors*

Offer low-dose (75 mg) daily aspirin or, if clear aspirin intolerance, clopidogrel†

But see new evidence from POPADAD trial in primary prevention of people with diabetes

*-Features of metabolic syndrome, strong early family history of CV disease, smoking, hypertension, existing CV disease, microalbuminuria

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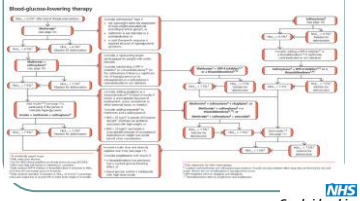
Management of Blood Glucose



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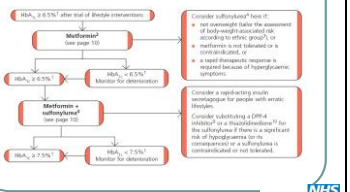
Management of Blood Glucose 2



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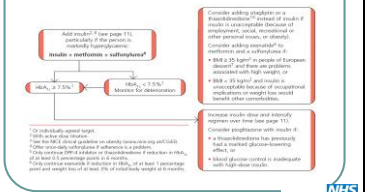
Management of Blood Glucose 3



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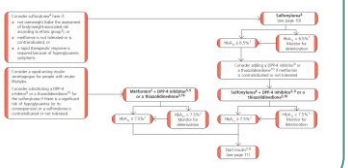
Management of Blood Glucose 4



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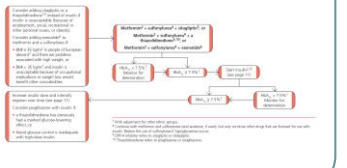
Management of Blood Glucose 5



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NICE Clinical Guideline: the management of type 2 diabetes

- Partial update of CG 66 (May 2008) to address role of newer drugs. Most remains unchanged
  - Monitoring of BP, lipids and BG
  - Diabetes Education programmes
  - Use of medications to manage BP, lipids and BG
  - Ongoing management and monitoring of microvascular effects and depression
- What has changed?
- New recommendations on medications to control BG
  - GLP-1 mimetic (exenatide), DPP-4 inhibitors (sitagliptin, vildagliptin) and glitazones (rosiglitazone and pioglitazone)

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Key Priorities for Implementation

- Patient Education – Offer structured education around time of diagnosis.
- Dietary Advice – Provide individualised and ongoing nutritional advice from a HCP with specific expertise and competencies in nutrition
  - Lifestyle management remains key to management of T2DM
- Setting a Target HbA1c
  - Involve person in decisions re target level (may be higher than 6.5%)
  - Avoid pursuing highly intensive management to less than 6.5%
- Self monitoring of Blood Glucose (SMBG)
  - Offer to newly diagnosed only as part of self management education

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Management of Blood Glucose

Glucose Control Strategy

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Setting a Target HbA1c

- Involve person in decisions about their individual target level which may be above that set for people with T2DM in general
- HbA1c value of 6.5% (or other higher level agreed with the individual) for diet controlled and people on one glucose lowering drug
- HbA1c value of 7.5% (or other higher level agreed with the individual) for people on two or more oral glucose lowering drugs
- Avoid pursuing highly intensive management to less than 6.5%

Measure HbA1c every 2-6 months (according to need) until stable on unchanging therapy then every 6 months

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Appendix 13 (Cont)

Glitazones (1)

- Increase insulin sensitivity + glucose uptake, reduce gluconeogenesis
- Known safety concerns – MHRA/CSM advice
  - Contraindicated in heart failure or history of HF
  - Incidence of HF increased when combined with insulin
- Cautions and safety concerns
  - Fluid retention and heart failure
  - Bone density loss and fracture risk
  - Macular oedema
- Cause increase in body weight, peripheral oedema
- Rosiglitazone may be associated with increased risk of cardiac ischaemia
  - Not recommended for use in patients with IHD, PAD, contraindicated in ACS
  - May increase the likelihood of MI or cardiovascular disease
  - Rosiglitazone associated with dislipidaemia, (raised LDL, TGs)

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Summary - Recommendations for BG Control (NICE) - 2

- Are there alternatives to insulin therapy?
  - Sitagliptin ▼ or a glitazone can be considered for triple therapy with Metformin plus SU if insulin unacceptable or inappropriate
- Exenatide may be considered for triple therapy in addition to metformin and SU (if HbA1c > 7.5% or higher agreed level) where
  - BMI>35kg/m^2 and specific psychological or medical problems with high weight
  - BMI>35kg/m^2 and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity related co-morbidities
- *Exenatide should only be continued if there is a reduction in HbA1c of at least 1% and a weight loss of 3% of initial body weight at 6 months*

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Starting Insulin Therapy (NICE)

- If other measures do not keep HbA1c <7.5% (or agreed target) discuss benefits and risks of insulin
- Initiate with structured programme
- Begin with human NPH (isophane) insulin at bedtime or b.d. depending on need

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Self-monitoring of blood glucose

Self-monitoring

- Offer self-monitoring of plasma glucose to a person newly diagnosed with type 2 diabetes only as an integral part of his or her self-management education. Discuss its purpose and agree how it should be interpreted and acted upon.

Make available to:

- Those on insulin
- Those on oral medication to provide information on hypoglycaemia
- Assess changes during medication or lifestyle changes, or illness
- Ensure safety during activities, including driving

Assess at least annually in a structured way:

- Self-monitoring skills
- Quality and appropriate frequency of testing
  - The use made of results obtained
  - The impact on quality of life
  - The continued benefit

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Self Monitoring of Blood Glucose (SMBG)

- Two new studies suggest that newly diagnosed people with T2DM are unlikely to gain any benefit from monitoring blood glucose themselves. SMBG may result in lower quality of life.
- O'Kane M et al Efficacy of self monitoring of BG in patients with newly diagnosed T2DM (ESMON Study BMJ April 2008)
  - Adding SMBG structured education did not produce greater reductions in HbA1c cf education alone
  - No differences in reported hypoglycaemia, OHA use or BMI
  - Patients in SMBG gp were significantly more depressed than control gp
- Simon J et al Cost effectiveness of SMBG in patients with non insulin treated T2DM economic evaluation from DiGEM trial (BMJ April 2008)
  - SMBG was associated with reduced health related QoL thought to be due to increased levels of depression and anxiety

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Glitazones (1)

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  - May increase the likelihood of MI or cardiovascular disease
  - Rosiglitazone associated with dislipidaemia, (raised LDL, TGs)

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Glitazones (2)

- Only one glitazone study– PRO-ACTIVE deigned to assess cardiovascular outcomes (pioglitazone)
  - No statistically significant difference between groups for primary endpoint
- No convincing evidence for improved clinical outcomes
- If glitazone thought to be appropriate, pioglitazone appears to be safer
- Recommended preferred choice – Pioglitazone (formulary choice)
- Combination products - No evidence for improved compliance or HbA1c
  - Removes capacity to titrate maximise metformin concentration
  - Not licensed for initiation

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PRO-Active Study

- Average observation was 35.4 months
- Primary endpoint – Composite of all-cause mortality, non-fatal MI, stroke, ACS, endovascular/surgical intervention
  - *no significant difference between groups*
- Main secondary endpoint – Composite of all-cause mortality, non-fatal MI, stroke
  - NNT= 48 over 34.5 months
  - p = 0.27
  - but no difference in those taking statins
- Heart Failure requiring hospital admission
  - NNH= 62 over 34.5 months
  - p = 0.007

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Oral Hypoglycaemics: Old vs. new drugs

- Systematic review of 216 studies and 2 earlier SRs of oral hypoglycaemics to January 2006 concluded that older agents have similar or superior effects to newer, more expensive agents on glycaemic control, lipids and other intermediate endpoints (body weight, BP, adverse effects, etc.)
  - (Older agents: metformin, SUs. Newer agents: glitazones, α-glucosidase inhibitors, meglitinides)

Glucose lowering effectiveness

Metformin	1-2%
Sulphonylureas	1-2%
Glitazones	0.5-1.5%
Gliptins sitagliptin, vildagliptin	~ 0.7%
GLP agonists (exenatide)	~1.0%

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Incretin Therapy

- GLP-1 agonists (Exenatide, liraglutide)
  - Stimulate glucose dependent insulin secretion
  - Glucagon Suppression
  - Delays gastric emptying
  - GLP-agonists rapidly inactivated by the enzyme dipeptidyl dipeptidase 4
- DPP-4 inhibitors (Gliptins – Sitagliptin, vildagliptin)
  - Inhibit dipeptidyl dipeptidase - 4
  - Enhance levels of incretin hormones (eg GLP1)
  - Enhance insulin, reduce glucagon
  - Reduce BG Levels

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GLP-1 Agonists

- Exenatide
  - Licensed in combination with metformin and / or SUs
  - Twice daily s.c. injection within 60min of main meal
  - HbA1c reduction approx 0.9 – 1.0%
  - Currently secondary care prescribing only
  - Once weekly preparation in development
- Liraglutide
  - Licensed in combination with metformin and / or SUs
  - Licensed in combination with metformin and glitazone
  - Once daily
  - Currently red listed

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DPP-4 Inhibitors - Gliptins

- Possibly weight neutral
- Increase ß-cell activity
- No evidence more effective than current options
- No outcome, morbidity or mortality data
- Long term adverse event profile not known
- No effect on insulin resistance
- Key interventions lifestyle, metformin
- Vildagliptin submission was delayed – safety concerns, now licensed

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DPP-4 Inhibitors - Gliptins

- Sitagliptin
  - Licensed in combination with metformin or glitazone or SU or metformin and SU
  - Oral 100mg od
  - HbA1c reduction approx 0.7%
- Vildagliptin
  - Licensed in combination with metformin or glitazone or SU (not triple therapy)
  - HbA1c reduction approx 0.7%

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DPP-4 Inhibitors - Gliptins

- Sitagliptin
  - Licensed in combination with metformin or glitazone or SU or metformin and SU
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  - HbA1c reduction approx 0.7%

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Management of Cardiovascular Risk

- Blood pressure management
- Management of blood lipids
- Antithrombotic therapy

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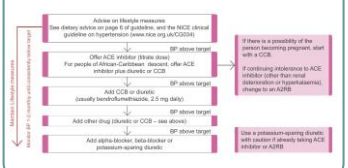
Appendix 13 (Cont)

Algorithm for BP Control (1)



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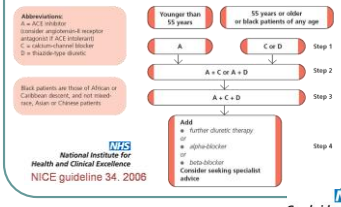
Choosing Drugs for patients newly diagnosed with hypertension



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Which Antihypertensive?

First-line BP lowering therapy should be a once-daily, generic ACE inhibitor

- Exceptions to this are:
  - People of African-Caribbean descent, who should receive an ACE inhibitor plus either a diuretic or a generic calcium-channel blocker (CCB)
  - Women for whom there is a possibility of becoming pregnant, who should receive a CCB
  - For a person with continuing intolerance to an ACE inhibitor (other than renal deterioration or hyperkalaemia), substitute an angiotensin-II receptor antagonist (A2RA)* for the ACE inhibitor

* Also called an angiotensin-II receptor blocker (A2RB)

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Evidence from ALLHAT

The Antihypertensive and Lipid Lowering treatment to Prevent Heart attack Trial – ALLHAT

- 33,357 people aged >55 with hypertension and at least one other CHD risk factor - randomised to chlorthalidine, amlodipine or lisinopril (mean follow up 4.9 years)
  - Target BP, 140/90mmHg. Titration of study drug and added open label therapy
- No significant differences between treatments for primary outcome (combined fatal CHD or non- fatal MI).
  - First line use of thiazides, ACE inhibitor, or CCB were similarly effective in reducing the risk of major CV events
  - There was no evidence of superiority for CCBs or ACE inhibitors compared with a thiazide-type diuretic in patients with diabetes or IFG
- Differences in secondary outcomes – Diuretic superior to CCB and ACE-I
  - Amlodipine had higher 6 year rate of HF than chlorthalidone
  - Lisinopril had higher 6 year rate of stroke, combined CVD and HF than chlorthalidone
  - NB: Fourth treatment arm with doxazosin was stopped prematurely (median 3.3 years) because of advence CV rate (stroke, CVD and HF)
- Concluded that chlortalidone was unsurpassed in lowering BP and reducing CV outcomes
- Thiazides in patients with diabetes are safe and well tolerated
  - If there are no compelling reasons to favour one recommended second line therapy over one another, a thiazide diuretic is an appropriate choice in most

JAMA 2002;288:2981-2997. Wheton P, et al. Arch Intern Med 2005;165: 1401–1409. MeHMC Bulletin No. 27 March 2007

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Evidence from ALLHAT

- Over 30,000 patients (excluding doxazosin arm)
- First line use of thiazides, ACE-I or CCB were similarly effective in reducing the risk of major CV events
- There was no evidence of superiority for CCBs or ACE-I compared with thiazide-type diuretic in patients with diabetes or IFG
- No differences in fatal or non-fatal CHD between lisinopril (ACE) and chlortalidone (diuretic) groups. Patients taking amlodipine had higher risk of fatal or non-fatal CHD, and higher risk of heart failure, than those taking chlortalidone (2º outcomes)
- More cases of diabetes (FG>6.9mmol/l) detected in chlorthalidone group – however absolute differences were small
- Patients randomised to chlortalidone were not disadvantaged for any other outcomes compared to those in other treatment arms
- The authors concluded that thiazide diuretics are unsurpassed for lowering blood pressure and reducing CV outcomes

Wheton P, et al. Arch Intern Med 2005; 165: 1401–09

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Further Evidence

- BPLTTC - Blood Pressure Lowering Treatment Trialists Collaboration - Meta-analysis of 27 trials
  - Included 158,709 participants, 33,395 with diabetes
  - Found that CV events reduced to a similar extent by regimes based on diuretic, ß-blocker, ACE-I, A-II-A or CCB
  - Chlorthalidone, amlodipine and lisinopril similarly effective in reducing BP
  - HF more common in patients with t2DM than chlorthalidone
- ADVANCE BP Study – RCT
  - 11,140 patients >55 with T2DM plus CV disease or at least one risk factor
  - Perindopril and indipamide vs placebo (concurrent medications continued)
  - Combined major macrovascular and microvascular events reduced by 1.3%, NNT=77, RRR 9%, p=0.04
  - No significant differences when macro and micro events analysed separately
  - Death from CV disease and from any cause reduced by 0.8% (NNT= 25, RRR18%, p=0.03) and 1.2% respectively
- STUDY CONFIRMS THAT
  - lowering BP in patients with T2DM reduces CV complications and death
  - Thiazide remains good first choice in most

BPLTTC. Arch Intern Med 2005;165:1410-1419 Lancet 2007; Ref

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ACE-Is vs A-II-As

Two new studies

ONTARGET Study

- No significant difference in primary outcome (CV death, MI, stroke or hospitalisation for HF) with between telmisartan, ramipril or the combination
  - Compared with telmisartan alone, more ramipril patients discontinued due cough (NNH 32) or angioedema (NNH 500)
  - Compared with ramipril alone, more telmisartan patients discontinued because of hypotensive symptoms (NNH 100)

TRANSCEND Study (Patients intolerant of ACE-Is)

- No significant reduction in the primary outcome (CV death, MI, stroke or hospitalisation for HF) with telmisartan compared with placebo

Lancet 2 Med 2008;368:1547-1648. Lancet 2008;372:1174-1183

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ACE-Is vs A-II-As - Summary

- ACE-Is remain first choice
- A-II-As are an alternative if ACE-I not tolerated because of cough
- A-II-As not supported by outcome evidence
- Combination treatment (RAS drugs) is not appropriate for the prevention of CV events in people with T2DM
  - It is no more effective and is associated with more adverse events (hypotension, syncope, renal dysfunction and hyperkalaemia

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Role of Statins in Type 2 Diabetes

- After symptom control (smoking cessation if relevant) and control of blood pressure
- Benefits appear to be around a 20–30% relative risk reduction regardless of age, gender, lipid levels.
- Baseline risk is the key to the size of the absolute benefits
- Should **all** those with type 2 diabetes be on a statin?
- Which statin:
  - Evidence is for simvastatin 40mg/day or atorvastatin 10mg/day
  - Local and national policy – simvastatin 40mg/day
  - Safety concerns with rosuvastatin (don't forget cerivastatin)

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Management of Blood Lipids (1)

- Offer generic simvastatin (to 40mg) or a statin of similar efficacy + cost
- For people:
  - Aged 40+ years and normal to high CV risk for someone with type 2 diabetes
  - Aged 40+ years and low CV risk for someone with type 2 diabetes but CV risk >20%/10 years when assessed using UKPDS risk engine
  - Aged under 40 years and poor CV risk factor profile
  - High serum triglycerides (may be necessary to offer fibrate if >4.5mmol/l
- Assess lipid profile and modifiable risk factors 1–3 months after starting therapy. Continue to monitor annually
- If possibility of becoming pregnant, discuss issues around statin use and agree next step with patient.

Type 2 diabetes: the management of type 2 diabetes. NICE Clinical Guideline 87 May 2009

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Management of Blood Lipids (2)

- Increase to simvastatin 80mg daily unless total cholesterol <4.0mmol/L or LDL-cholesterol <2.0mmol/L
  - The health economic analysis suggested titration to simvastatin 80mg was highly cost effective in those whose lipid-levels were not controlled to target levels of 4.0/2.0mmol/L irrespective of presence or absence of diagnosed CVD
- If there is existing or newly diagnosed CV disease or increased albumin excretion rate, consider intensifying therapy (with a more effective statin or ezetimibe)* to achieve a total cholesterol level below 4.0mmol/L or LDL-cholesterol level below 2.0mmol/L
  - In those with CVD the health economic analysis suggested that uptitration from simvastatin 80mg to a more efficacious statin (modelled as atorvastatin 80mg) was cost-effective if the titration targets were not met on simvastatin

*In line with NICE TAG 94: statins for prevention of CV events and NICE TAG 132: ezetimibe for primary hypercholesterolaemia

Type 2 diabetes: the management of type 2 diabetes. NICE Clinical Guideline 87 May 2009

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When to Initiate Fibrates

- Offer a **fibrate** (fenofibrate as first-line) if TG levels remain above 4.5 mmol/L despite attention to other causes (optimised glycaemic control)
  - In some circumstances, this will be before a statin has been started because of acute need (i.e. risk of pancreatitis) and because of the undesirability of initiating two drugs at the same time
- If cardiovascular risk is high (as is typical in people with type 2 diabetes), consider **adding a fibrate to statin therapy** if TG levels remain in the range 2.3–4.5 mmol/L despite statins

But safety issues with fibrates…

Type 2 diabetes: the management of type 2 diabetes. NICE Clinical Guideline 87 May 2009

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Antithrombotic Therapy

- Current NICE Guideline recommends in people with T2DM – Offer low dose aspirin (75mg) daily
  - for >50 years as long as BP controlled (<145/90)
  - Age < 50 and significant other CV risk factors
- There is good evidence that aspirin is effective for the prevention of secondary events, including those with T2DM Low dose aspirin is established in the secondary prevention of cardiovascular disease

What about primary prevention?

- More recent evidence from meta-analyses and the POPADAD trial suggest that in primary prevention, the benefits and harms from aspirin in this setting may be more finely balanced than was previously thought even in those estimated to be at higher risk of CV events (eg diabetes , raised BP).
- Low dose aspirin is not therefore routinely recommended for primary prevention

DTB 2009; Vol 47 (11):122-124

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Drug Safety Update

Volume 1, Issue 4 November 2007

Advice for healthcare professionals:

- Fibrates should be considered as first-line therapy only in patients with isolated severe hypertriglyceridaemia
- For patients with mixed hyperlipidaemia, fibrates may be used only when a statin or other effective treatments are contraindicated or not tolerated
- In patients with primary hypercholesterolaemia, the use of gemfibrozil may be considered, but only when a statin or other effective treatments are contraindicated or not tolerated
- Combination therapy with a statin and a fibrate should be used with caution and only when the benefits are expected to outweigh potential risks. Avoid concomitant use of gemfibrozil with a statin

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Kidney Damage

If diabetic nephropathy confirmed, offer ACE-I with dose titration to maximum dose (unless not tolerated)

- Substitute A-II-A if ACE-I not tolerated
- Maintain BP < 130/80mmHg if abnormal ACR (renal damage)
  - Or if retinopathy or cerebrovascular damage

Type 2 diabetes: the management of type 2 diabetes. NICE Clinical Guideline 87 May 2009

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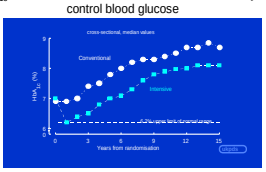
Appendix 13 (Cont)

Neuropathic Pain Management

- Offer tricyclic drug (amitriptyline) starting at low dose, titrate as tolerated
- If uncontrolled offer trial (to max dose) of gabapentin If uncontrolled offer alternative therapy (pregabalin or duloxetine) according to CPCT guideline
  - Stop if ineffective at maximally tolerated dose
  - Try another drug if SEs limit dose titration
- If uncontrolled, consider trial of opiate analgesia
- If uncontrolled discuss with person and seek assistance of local chronic pain management team if agreeable.
- If any of the above treatments are effective, consider reducing dose/stopping therapy following discussion and agreement with person concerned.

Glucose Control

HbA_{1c} will rise over time — no matter how hard we try to control blood glucose



Intensive BG control in T1DM

- Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications DCCT/EDIC Research Group
- Observational Data – Frequencies of serious complications in patients with T1DM are lower than reported historically.
- Incidence of complications appears to be substantially lower than those who started intensive BG control early on in their treatment
- Paper reinforces the current approach of aiming for intensive BG control in patients with T1DM
- In contrast to the evidence around T2DM

10-year follow-up of UKPDS

- Observational follow-up of the blood glucose part of the study
- Baseline differences in mean HbA1c levels lost by 1 year, but despite this…

There was a continued reduction in microvascular risk and emergent reduction in macrovascular risk seen with intensive vs. conventional therapy

- Significant risk reductions also persisted with metformin, in the sub-study of overweight patients
- BUT these are observational data
  - Needs comparison with original UKPDS RCT data
  - Does not provide evidence for early, very intensive glucose-lowering treatment for all patients with type 2 diabetes

There is still no convincing evidence that tight control of blood glucose in type 2 diabetes reduces CV risk

And we now have ACCORD, ADVANCE and VADT

ACCORD, ADVANCE and VADT

- Three large RCT set up to assess whether intensive glucose control strategies offered any advantage over standard therapies with regard to major CV events
- Found no significant improvements in macrovascular events with intensive glucose control
- In ACCORD, intensive BG lowering therapy was associated with an **increased** risk of death

The ACCORD Study

Randomise Controlled Trial - 10,251 patients (mean age 62 years) with T2DM and elevated CV risk. Set up to assess effects of intensive BG, BP and lipid lowering

Blood Glucose Lowering Arm

- Randomised to intensive glucose-lowering (target HbA1c <6.0%) or standard therapy (target HbA1c 7.0–7.9%)
- Primary endpoint (MI, stroke or CV death) did not differ between groups
- Intensive BG treatment stopped early, after 3.5 years, because of higher all-cause mortality

	Intensive therapy	Standard therapy	Hazard Ratio (95% CI)
Stable median HbA1c at 1 year	6.4%	7.5%	-
Primary endpoint (MI, stroke or CV death)	6.9%	7.2%	0.90 (0.78-1.04); P=0.16 Not significant
All-cause mortality	5.0%	4.0%	1.22 (1.01-1.46); P=0.04; NNH=95

ACCORD

- 10,251 patients with type 2 diabetes
- Average age 62
- Diabetes present for an average of 10 years
- Participants randomly assigned to treatment with any number of glucose lowering therapies
- Target HbA1c 6% or less
- All-cause mortality (5%v4%) and cardiovascular mortality (2.6%v1.8%) were higher in the intensive group of the study
- Study stopped early, after 3.5 years of follow up

What about ADVANCE?

- RCT of 11,140 patients (mean age 66 years) with T2DM and elevated CV risk
- Randomised to intensive treatment with gliclazide-based regime (target HbA1c<6.5% or less) or standard therapy (target based on local guidelines)
- Median follow-up 5 years
- Intensive therapy showed no significant effect on macrovascular events or all-cause mortality, but it did reduce nephropathy

	Intensive therapy	Standard therapy	Hazard Ratio (95% CI)
Mean HbA_{1c}	6.5%	7.3%	-
Macrovascular primary endpoint (MI, stroke or CV death)	10.0%	10.6%	0.94 (0.84–1.06); P=0.32 Not significant
Microvascular primary endpoint (new or worsening nephropathy or retinopathy)	9.4%	10.9%	0.86 (0.77–0.97); P=0.01; NNT=67
All-cause mortality	8.9%	9.6%	0.93 (0.83–1.06); P=0.28 Not significant

ADVANCE

- 11,140 participants
- Mean age 66, diabetes for 8 years
- Randomly assigned to **intensive** treatment with modified release gliclazide or standard therapy
- Target HbA1c 6.5% or less
- After 5 years follow up HbA1c 6.5% in intensive group and 7.3% in control group
- **No difference** in all-cause mortality, cardiovascular mortality or major cardiovascular events
- Difference detected in microvascular outcomes, mainly reduction in nephropathy.

The Veterans Affairs Diabetes Trial (VADT)

- Open-label RCT -1,791 people (mean age 60 years) with T2DM
  - Most did not smoke, had well-controlled BP and were taking a statin
- Randomised to intensive or standard glucose control with oral hypoglycaemic drugs (including rosiglitazone) plus insulin if necessary. Other CV risk factors were treated uniformly
- Over median follow-up of 5.6 years - intensive treatment to achieve a median HbA1c of 6.9% compared with standard control to a median of 8.4% did not statistically significantly reduce the risk of:
  - Major CV events (MI, stroke, death from CV causes, CHF, surgery for vascular disease, inoperable coronary disease, amputation for ischaemic gangrene), HR 0.88; 95% CI 0.74 to 1.05, P=0.14 or any of these component endpoints
  - All-cause mortality, HR 1.07; 95% CI 0.81 – 1.42; P=0.62
  - Any microvascular outcomes (ophthalmic, nephropathic or neuropathic)
- Patients in the intensive treatment arm were more likely to experience hypoglycaemic episodes

Managing blood glucose is important but, in isolation it is not the key to preventing morbidity and mortality

MeReC Bulletin 2004; 15: 1-4

What is basis of this?

Evidence base for the factsheet

- Stems from **observational** data
  - UKPDS35 – Stratton et al, BMJ 2000; 321: 405-412
  - Also EPIC Norfolk – Khaw KT et al, Ann Intern Med 2004; 141: 413-420 (TYPE 1 diabetes study)
- So what?
  - These papers generate a hypothesis – that reducing HbA1c results in reductions in CV events and mortality in type 2 diabetes
  - The UKPDS refutes this hypothesis, as it found little evidence for insulin/SU-based tight control of blood glucose

Targets in Type 2 Diabetes

	NICE	QOF
Blood Pressure	140/80mmHg 130/80mmHg -m/a	145/85
Blood lipids (CV risk)	TC < 4 LDL < 2	TC <5
HbA1c	Monotherapy -6.5% Dual therapy -7.5%	7%, 8%, 9%

When setting a target HbA1c …..

- Involve the person in decisions about their individual HbA1c target which may be above that set for patients with T2DM in general
- Encourage person to a maintain individual target unless SEs impair quality of life
- Offer therapy (lifestyle and medication) to help achieve and maintain target HbA1c
- Inform person with higher Hba1c that any reduction towards agreed target is advantageous to future health
- Avoid pursuing highly intensive management to levels of < 6.5%

Appendix 14

Academic Detailing: Planning Matrix T2DM

	Key Message	Features	Benefits (which Means that…)	Trust / Credibility	Suitable Questions
1	Although characterised by raised BG, T2DM is a cardiovascular disease associated with increased morbidity and mortality • there is inherently a higher cardiovascular risk in patients with T2DM • associated with overweight / obesity	Generally associated with obesity and insulin resistance c.f. T1DM where there is an absence of insulin	Can target therapeutic and non therapeutic interventions more effectively to reduce morbidity and mortality.	Evidence eg UKPDS Increasing awareness that cardiovascular risk is key in improving outcomes	What are the most important things to consider in management of patients with T2DM
2	Prioritisation of treatment is key to targeting the specific aspects of care and reducing morbidity and mortality associated with T2DM.	T2DM is a long term condition associated with poor long term outcomes if not managed	Can target therapeutic and non therapeutic interventions more effectively to reduce morbidity and mortality.	Evidence UKPDS	How would they prioritise the 5 most important things identified
3	Aggressive management of cardiovascular risk is the most effective intervention in reducing more serious complications, morbidity and mortality rather than tight control of glucose. Tight control (intensive management) of blood glucose is not the main priority in improving patient outcomes.	Requires consideration of a number of aspects of care for each individual. Aim to manage so have most impact on improving patient outcomes	Prevent / delay avoidable clinical problems / complications, patient suffering, admissions Minimise cost Human Financial / NHS	Evidence UKPDS Metformin Hypertension studies ALLHAT, BPLTTC, ADVANCE BP Lipid management Renal Studies (ACE-I / A-II-A)	What sources of information would they access to support their education in managing aspects of T2DM

	Key Message	Features	Benefits (which Means that…)	Trust / Credibility	Suitable Questions
4	The Hand Use to prioritise / remember approach to management in terms of most effective interventions – Lifestyle interventions are key and underpin management • Lifestyle interventions are key in prevention and treatment – Needs to be maintained • Stopping smoking • Management of BP most effective means of reducing CV risk after stopping smoking • Management of BP as if not more important then tight control of BP in reducing events • Stormin Metformin	Provides aide memoire to prioritise approach to management of individual patients	Improved patient care, reduction in complications Improved quality of life	Evidence As above	Have they a different aide memoire eg ABCDEFG?
5	Guidance to GPs on most appropriate first line and follow up drug choices for management of • BP • Lipids • BG • Nephropathy • Neuropathy • Aspirin	Knowledge, expertise and advice on evidence based medication choices. To achieve best clinical outcomes for patients In line with (actual) evidence based guidelines	GPs can use prescribing adviser as trusted source of information	You Provision of further information/background data/evidence to support recommendations following discussion.	

	Key Message	Features	Benefits (which Means that…)	Trust / Credibility	Suitable Questions
6	How can practice improve? • Follow best practice advice • Audit of patients outcomes to support decision making in concentrating efforts for management of various aspects of therapy. MRW can provide information / support • Get commitment from practice to o Increase prescribing of metformin o Reduce rosiglitazone. Initiate pioglitazone / managed switch to pioglitazone (reduce overall glitazones) o Cautious use of new drugs – starting/stopping criteria o Increase ratio metformin:metformin MR • Increase in prescribing of ACE-I/A-II-As for T2DM patients with m/a • Proportion of T2DM patients achieving BP <140/80mmHg • Proportion of T2DM patients with m/a achieving BP <130/80mmHg				

Academic Detailing: Planning Matrix T2DM

Aim of Session	**Areas of Controversy**	**Mandatory Literature**
To discuss approach to management of T2DM To promote better management (if possible) of T2DM by prioritisation of effort in managing various aspects of the disease to prevent progression and reduce complications of diabetes. To consider the most effective and evidence based therapeutic (and non-therapeutic) interventions to reduce morbidity and mortality and outcomes that matter to patients	Blood Glucose or Blood Pressure? ACE-I versus A-II-As	NICE Guideline on T2DM CG66 and CG87 (Update) UKPDS Detail Aid, Support Slides Access to original sources MHRA/FDA (Glitazones) DTB - Glitazones
Possible 'Starters for 10'	**Questions to Ascertain Closure**	**Materials to Take With You**
What do you consider as the most important factors in managing patients with T2DM. Does the practice have a specific approach? Eg Nominated GP, PN How would the practice members prioritise approach to management	Do they think that this approach differs from their current approach? Do they think that there are changes that they could make? Eg • Increase use of metformin • 1st, 2nd and 3rd line choice of antihypertensive • Switch/reduce glitazone prescribing How could we support them in any agreed actions?	NICE Guideline on T2DM CG87 (Update)

Appendix 15

Academic Detailing: Planning Matrix NSAIDs

	Key Message	Features	Benefits (which means that…)	Trust / Credibility	Suitable Questions
1	The key and most important message relates to Safety	Aim to prevent unnecessary or avoidable harm	Prevent serious clinical outcomes	Obvious	
2	All NSAIDs (including COX-IIs) carry a risk of serious SEs • Cardiovascular • Cardiorenal • Gastrointestinal			Evidence MHRA warnings	What do they perceive as risks associated with prescribing of NSAIDs? How does this fit in with the NICE guidance?
3	Need to consider approach to NSAID prescribing to minimise patient risk High volume prescribing – More attributable events	To prevent adverse events, SUEs	Minimise risk to patient population Practice / GP reputation Minimise cost Human Financial / NHS		Have they had experience of patients with AEs attributable to NSAIDs (serious or otherwise?)
4	Need to assess the risk for individual patients and tailor drug choice / treatment Including non-NSAID options to individual patient to minimise risk	To prevent adverse events, SUEs	Minimise risk to individual patient Prevent avoidable clinical problems, suffering, admissions		How do they approach management of risk in individual patients?

	Key Message	Features	Benefits (which means that…)	Trust / Credibility	Suitable Questions
5	Best Practice Points – List • Copy of list for each GP • Steps to 'NSAID heaven'	As above	As above	As above	Would they consider adopting approach for each patient? Would they consider review of current patients on repeat?
6	Anticipated Outcome / Objective How can practice improve? • Follow best practice advice • Audit patients on NSAIDS (and COX-IIs) As defined in presentation • If appropriate get commitment from practice to perform audit to reduce NSAID prescribing • Expect ○ ↓ Diclofenac prescribing ○ ↓ COX-II prescribing ○ ↓ Overall NSAID prescribing ○ If NSAID has to be used, reflected by relative ↑ in proportion of ibuprofen, naproxen c.f. diclofenac ○ Increase in prescribing of topical NSAIDs ○ If NSAID has to be used, reflected by increased proportion of gastroprotection				

Academic Detailing: Planning Matrix NSAIDs

Aim of Session	**Areas of Controversy**	**Mandatory Literature**
To discuss approach to management of OA and related conditions where prescribing of an NSAID might be an option. To raise awareness of risk and safety issues around the use of NSAIDs. To promote safer prescribing of NSAIDs and use of alternative medications where possible	Alleged improved safety of COX-IIs Use of meloxicam and etodolac Glucosamine	MeReC NICE CG 59 Feb 2008 MHRA
Possible 'Starters for 10'	**Questions to Ascertain Closure**	**Materials to Take With You**
	Do they think that there are changes that they could make Would it be an idea to review patients according to the audit criteria? Before next visit Could do it for them?	ePACT data demonstrating practice prescribing of NSAIDs Comparative data

Appendix 16

Recruitment Process - Summary Flowchart

Study Title - An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Recruitment -
Study details sent to GP Practices in Cambridgeshire PCT
- Letter of invitation to participate in study
- Study Information Sheet (1)
- Expression of interest to participate
- Chief Investigator contact details

↓

Interested practices request practice visit from CI to discuss study design / participation requirements

↓

Interested Practices Consent to participate

↓

Intervention

↓

Practice Outreach Visits by Primary Care Pharmacists
- Baseline Visit
- Follow Up Visits (3)

Visit content includes;
Provision of evidence-based prescribing support
Written educational support materials
Audit and feedback on prescribing

Study duration ~ 12 months

Qualitative Evaluation
of GP Prescribing Behaviour
(Semi-structured interviews)

↓

Recruitment of GP participants
from intervention practices

↓ ↓

Pre-intervention
Study Details (information sheet (2)) provided to individual GPs prior to baseline visit

↓

Interested GPs
Consent

Post-intervention
Study details(information sheet(2)) provided to individual GPs post intervention
(~ 12 months after baseline visit)

↓

Interested GPs
Consent

Appendix 17

Medicines Management Newsletter – 'Prescribing Matters'

Article published to raise awareness of study

EB or not EB

What is the question?

There are a number of questions regarding evidence based practice – for example:

- What does evidence based practice mean to you?
- How does it inform your decision making in relation to prescribing?

Participation in a local research study could help provide the answers.
The study will investigate how evidence based prescribing support provided by clinical pharmacist prescribing advisers may inform GP decision making and influence prescribing behaviour.

Invitation letters and Study Information Sheets will shortly be distributed to GP Prescribing Leads, Senior Partners and Practice Managers for information.
If you think you may be interested in taking part in the study, please look out for the study details.

If you have any queries or require further information, please do not hesitate to contact Melanie Whittick , Consultant Pharmacist, NHS Cambridgeshire.
Tel: 01480 354360
e-mail: melanie.whittick@cambridgeshire.nhs.uk

Appendix 18

Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN
01480 354360

Dear Senior Partner
GP Prescribing Lead
……Practice

Re: Research Project: Evidence-Based Prescribing Support from Primary Care Prescribing Advisers

I am writing to invite you to take part in a research study. The study is investigating how prescribing support by primary care prescribing advisers may influence the prescribing behaviour of GPs and promote incorporation of the evidence-based information into the clinical decision-making process.

The project is being carried out as part of a Professional Doctorate being undertaken at the School for Health, University of Bath.

Please find enclosed an information sheet which describes why the research is being done and what it would involve for you and your practice. If you would like the opportunity to discuss the project further and what it would mean for the practice, I would be happy to meet with you

Please also feel free to contact me on the above number or by e-mail to ask me if there is anything that is not clear or if you would like more information about the study.

If you are interested in taking part, please complete the enclosed an 'Expression if Interest' form and return to me at the above address and I will contact you accordingly.

Yours sincerely

Melanie Whittick BSc MSc MRPharmS
Consultant Pharmacist
e-mail:melanie.whittick@cambridgeshire.nhs.uk

Cc: Practice Manager

Appendix 19

Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN

Study Information Sheet (1) Version 1, 30.11.08

Information About the Research

Study Title: An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Researcher: Melanie Whittick, Cambridgeshire PCT

Supervisor: Marjorie Weiss
Professor of Pharmacy Practice & Medicine Use, University of Bath

Your practice is being invited to take part in a research study. The study is investigating how prescribing support by primary care prescribing advisers may influence the prescribing behaviour of GPs and promote incorporation of the evidence-based information into the clinical decision-making process.

Before you decide, you need to understand why the research is being done and what it would involve for you and your practice. Please take time to read the following information carefully and discuss with other members of your practice. Please ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of the study is to investigate whether dedicated evidence-based prescribing support delivered by primary care clinical pharmacists (prescribing advisers) to GP practices can influence prescribing behaviour and promote uptake of evidence-based information into the clinical decision-making process by GPs. In order to gain an understanding of the impact of the prescribing support and its potential value in practice, GP perceptions, attitudes and beliefs will also be explored. The results of the study may have implications for the way primary care medicines management services are delivered in the future.

The project is being carried out as part of a Professional Doctorate being undertaken at the School for Health, University of Bath.

Why have I been invited?

You have been invited to take part in the study because you represent a Cambridgeshire GP practice. Local practices are being invited to participate in the study.

Does the practice have to take part?

Participation is voluntary. It is up to you and your partners to decide. Details of the study are included in this information sheet, which you may keep. Please read and share the information about the study with your partners. If you do decide to take part, you or another nominated GP will be asked to sign a consent form on behalf of the practice. You are free to withdraw at any time, without giving a reason. This would not affect your relationship with the PCT (or service you receive from the Medicines Management Team) in the future.

What will happen to the practice if we take part?

Participation in the study will involve the following:

Randomisation to 'the intervention' or control (no intervention) groups.

For Practices allocated to the intervention group:

Baseline visit.

GPs and healthcare professionals in the practice will be invited to attend a practice-based meeting at which the evidence-base relating to two pre-specified therapeutic topics will be presented and discussed. Succinct summaries on the therapeutic topics will be disseminated as handouts to practice GPs and other HCPs involved in the visits. Additional copies will be provided for members of the practice not able to attend the visit meeting. Prescribing data reflecting current prescribing trends for the therapeutic topics containing anonymised comparative data for practices in the PCT will also be provided to inform discussion.

Follow-up visits

Practices will receive three follow-up visits 4 months apart. Meeting agendas will be based on the predetermined therapeutic topics. Updated evidence-based materials will be prepared for each visit if new information is available. Updated prescribing data reflecting current prescribing trends will be provided to inform discussion. Additional copies of therapeutic topic summaries will be available. Audit and feedback reflecting prescribing volume in relation to the therapeutic topics during the study period will be based on PACT data.

The prescribing adviser will summarise discussions, document any agreed actions and send a summary to the practice after baseline and follow-up visits

It is anticipated that the baseline visit may take between 1-1½ hours with follow-up visits lasting up to an hour. Participating practices will be involved in the study for 12 months. It is anticipated that the overall study timeframe will be 18-24 months.

Non-intervention practices (control) will receive written materials only.

Participating practices will continue to receive usual medicines management support and communications from the Medicines Management Team. No element of the Medicines Management Team function will be withheld from intervention or control practices.

Patient Outcomes

In order to assess the impact of the intervention on patient outcomes, pre-intervention (baseline) and post-intervention audit on patient data will be performed for a number of pre-specified patient outcomes, which relate to the therapeutic topics. Individual patient notes will not be accessed for the purposes of this study and no patient identifiable data will be removed from practices. Practice permission will however be sought from intervention and non-intervention practices for access to audit data. (NB: Members of the Medicines Management Team currently supporting prescribing initiatives in practices routinely access patient notes in the course of their work and are bound by a contractual confidentiality clause as healthcare professionals working in the NHS).

Qualitative Evaluation

The clinician perspective in terms of delivery of the intervention to improve uptake and incorporation of evidence into the clinical decision-making process and the feasibility of the intervention in practice will also be sought through qualitative methodologies both before and after the intervention.

The qualitative evaluation will involve semi-structured interviews with individual GPs. Details are provided in the accompanying 'Participant Information Sheet – Qualitative Evaluation'. Separate consent will be obtained for this aspect of the study.

What will the practice have to do?

Participating practices will be asked to commit to the four visits as described previously. All GPs and other healthcare professionals working in the practice who may influence prescribing behaviour will be invited to attend. Although it may not be possible for all GPs to attend on a particular occasion, it is intended that the majority will be available to participate in each meeting.

Research suggests that short (lunchtime) meetings may be an appropriate circumstance in which to engage with practitioners on such topics. Practices may chose to have a lunchtime meeting or arrange an alternative time.

Practices will be asked to consent for the researcher (member of the Medicines Management Team) to access the practice system to collect audit data pre-intervention and post-intervention.

What is the intervention that is being tested?

The intervention is a complex intervention that is, an intervention that contains several interacting components. It will consist of a number of known approaches for influencing healthcare professional behaviour. It will be centred on interactive practice meetings based on face-to-face communication (academic detailing) with clinical pharmacists and incorporate additional approaches including audit and feedback and provision of supporting education materials. A key component of this study is that the therapeutic messages are evidence-based.

The pharmacist prescribing advisers will be trained in detailing techniques and will have received clinical training in the therapeutic topics and the supporting evidence-base.

What are the possible benefits of taking part?

You will have the opportunity as a group to discuss up to date evidence-based therapeutics with prescribing advisers who will be able to communicate pre-appraised evidence-based information thus removing the burden for GPs of seeking evidence at the point of prescribing. It is anticipated that there may be an associated improvement in patient care as measured by pre-determined clinical outcomes.

What are the possible disadvantages and risks of taking part?

There are no perceived disadvantages of taking part.

What will happen to the results of the study?

The results of the study will be written up as part of my doctoral thesis. Results will be shared with participating practices and more widely within the PCT. The results of the research may be published in peer reviewed scientific journals and disseminated through conference presentation.

Who is organising and funding the research?

The project is being led by Melanie Whittick as part of her Professionals Doctorate at Bath University. An application for separate funding may be sought through the National Institute for Health Research, Research for Patient Benefit Scheme.

Who has reviewed the study?

The study has been reviewed by the following authorities:

Ethical Approval has been given by the Cambridgeshire 4 Research Ethics Committee.

CamSTRAD. The study meets the Research Governance Requirements for Peterborough and Cambridgeshire NHS Trusts (Primary Care).

University of Bath, School for Health School Research Ethics Approval Panel

Further information and contact details

If you wish to discuss the study in more detail or require further information, please contact the researcher.

Researcher Melanie Whittick
Medicines Management
Cambridgeshire PCT
Hunts Area Offices
California Road
Huntingdon
Cambs.
PE29 1BN
e-mail: melanie.whittick@cambridgeshire.nhs.uk

Thank you for taking the time to read this information sheet. If you are interested in taking part in the research project, please fill in the attached 'Expression of Interest' form or e-mail me at the above address and I will contact you to discuss participation.

Expression of Interest

Re: Research Study

I / We are interested in taking part in the research Study: Evidence-Based Prescribing Support from Primary Care Prescribing Advisers

GP Signature……

Name ……

On behalf of

…… Practice
(Practice Stamp)

Please return to:

Melanie Whittick
Consultant Pharmacist
Medicines Management
Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN

Appendix 20

NHS Cambridgeshire
Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN

Practice Consent Version 2, 29.04.09

CONSENT FORM

Title of Project: An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Name of Researcher: Melanie Whittick

To be completed on behalf of Practice by senior partner or nominated GP.

Please initial box

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study on behalf of …… Practice. ☐

2. I confirm that I have discussed the study with my partners who have also had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

3. I understand that participation of the Practice is voluntary and that as a practice we are free to withdraw at any time without giving any reason and the practice relationship with the PCT will not be affected in any way. ☐

4. I understand that audit data relating to patient outcomes will be accessed and collected during the study and may be looked at by individuals from the PCT Medicines Management Team where it is relevant to the practice taking part in this research. No patient identifiable data will be removed from the practice. I give permission for these individuals to access practice data. ☐

5. I confirm that my practice colleagues have delegated authority to me to consent to participation in this study on behalf of the practice under the terms specified above. The Practice consents to participation in the above study. ☐

_____ _____ _____ _____
Name of Signatory Date Signature
On behalf of participating practice

_____ _____ _____ _____
Name of Person taking consent Date Signature
On completion, one copy to be held in research study files and one copy for practice files

Appendix 21

NHS
Cambridgeshire
Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN
01480 354360
2nd August 2010

Re: Research Study: An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Dear

As you are aware, your practice has agreed to participate in the above study. Baseline practice visits are currently being arranged for intervention practices with allocated pharmacists. The practice visits are centred on your practice GP team meetings. All GPs are invited to attend the meetings and participate as part of the study. Practice nurses and the practice manager are also invited to attend.

In addition to the quantitative evaluation, I will be carrying out a qualitative evaluation which is embedded in the main study. I am therefore seeking individual GP participants to take part in a semi-structured interview before the study intervention starts. (I will also seek additional GPs to participate in a semi-structured interview at study completion).

Please find attached the information sheet for the qualitative evaluation. I would be grateful if you would read the information and if possible discuss with / circulate to your GP colleagues. I will contact you in the near future to discuss possible participation in the qualitative evaluation.

I will also contact you before baseline visits to confirm that arrangements are in place for the baseline visit.

If you have any queries, please do not hesitate to contact me.

Kind regards,

Melanie Whittick BSc, MSc, MRPharmS
Consultant Pharmacist

Cc: Practice Manager / Study Contact

Appendix 22

NHS
Cambridgeshire
Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN

Study Information Sheet (2) Version 1, 30.11.08

Information About the Research – Qualitative Evaluation

Study Title: An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Your practice has agreed to take part in a research study. The study is investigating how prescribing support by primary care prescribing advisers may influence the prescribing behaviour of GPs and promote the incorporation of the evidence-based information into the clinical decision-making process.

Details of the study are provided in Study Information Sheet (1)

The study is employing a mixed methods approach. Within the main study is a qualitative evaluation of the intervention delivered in practice. You are being invited to take part in this part of the study. This information sheet provides details of this aspect of the study.

Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss with other members of your practice. Please ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

The purpose of the qualitative evaluation is to explore GP perceptions, attitudes and beliefs before and after delivery of the intervention and to gain an understanding of the impact and feasibility of the intervention and its potential value in practice. The clinician perspective in terms of delivery of the intervention to improve uptake and incorporation of evidence into the clinical decision-making process will be sought.

Why have I been invited?

You have been invited to take part in this part of the study because you are a GP based in one of the practices participating in the study allocated to receive the intervention.

Do I have to take part?

Participation is voluntary. It is up to you to decide. Details of the study are included in this information sheet, which you may keep. If you do decide to take part, you will be asked to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect your relationship with the PCT or service you receive from the Medicines Management Team in the future.

What will happen to me if I take part?

Participation in the study will involve participation in a semi-structured interview with a researcher trained in conducting interviews either before or after implementation of the intervention in the practice. The interview will last up to one hour and take place at a suitable time and date in your preferred location in the practice.

The researcher will ask you about your experience of the intervention and your views on evidence-based practice. The interview will be tape-recorded and subsequently transcribed. You will be asked to sign a consent form for permission to tape record the interview. Anonymised excerpts of transcripts may be quoted in any potential publications or presentations arising from the study for which your permission will also be sought.

Will my taking part in the study be kept confidential?

Information obtained from the interview will not be identifiable. The interview tapes and transcripts will be identified by a study code. Your name and any other identifying information will not be used. Interview tapes and transcripts will be stored securely in a locked cabinet. Interview tapes will be destroyed once data has been transcribed and verified.

What are the possible benefits of taking part?

There are no direct benefits to you in taking part. However, it may lead to a greater understanding of the prescribing support needs of GPs in practice and development of the role of the prescribing adviser in practice.

What are the possible disadvantages and risks of taking part?

There are no perceived disadvantages of taking part.

What will happen to the results of the study?

The results of the study will be written up as part of my doctoral thesis. Results will be shared with participating practices and more widely within the PCT. The results of the research may be published in peer reviewed scientific journals and disseminated through conference presentation.

Who has reviewed the study?

The study has been reviewed by the following authorities:

Ethical Approval has been given by Cambridgeshire 4 Research Ethics Committee.

CamSTRAD. The study meets the Research Governance Requirements for Peterborough and Cambridgeshire NHS Trusts (Primary Care).

University of Bath, School for Health School Research Ethics Approval Panel

Further information and contact details

If you wish to discuss the study in more detail or require further information, please contact the researcher.

Researcher Melanie Whittick
Medicines Management
Cambridgeshire PCT
Hunts Area Offices
California Road
Huntingdon
Cambs.
PE29 1BN
e-mail: melanie.whittick@cambridgeshire.nhs.uk

Thank you for taking the time to read this information sheet. If you are interested in taking part in this part of the research project, please fill in the attached 'Expression of Interest' form or e-mail me at the above address and I will contact you to discuss participation.

Appendix 23

NHS
Cambridgeshire
Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN

Semi-Structured Interview Consent Version 1, 30.11.08

CONSENT FORM

Title of Project: An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour**.**

Name of Researcher: Melanie Whittick

Please initial box

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my rights being affected. ☐

3. I understand that the interview will be tape-recorded and transcribed and excerpts may be looked at by responsible individuals from the research team. I give permission for the interview to be tape recorded. ☐

4. I understand that anonymised excerpts may be quoted in the resulting thesis and possibly included in written documents including publications in peer reviewed journals. I give permission for direct quotations to be published where it is relevant to my taking part in this research. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

On completion, one copy to be held in research study files and one copy for participant

Appendix 24

NHS Cambridgeshire
Hunts Area Offices
California Road
Huntingdon
Cambridgeshire
PE29 1BN
01480 354360
March 2012

To: GP Prescribing Lead
…… Practice

Dear Dr

Re: Research Study: An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

As you are aware, your practice took part in the intervention phase of the above study which involved practice visits with a nominated primary care pharmacist which were centred on your practice GP team meetings.

The practice visits are now complete. I am writing therefore to thank you and your partners for participating in the study. I am grateful for your time and commitment to the study objectives and I would also be grateful if you will pass on my thanks to your partners and other staff who may have been involved in the study.

I am currently embarking on the process of analysing both the quantitative and qualitative data collected as part of the evaluation, then progress to write up the project. I anticipate that this will take some time and hope to be able provide formal feedback to your practice once this is complete.

Once I have completed the data analysis, I should be able to provide interim feedback, particularly on the quantitative elements of the study, including e-PACT data which demonstrates some interesting trends, particularly in the use of NSAIDs. Please let me know if you would be interested in such feedback.

Thankyou again for your participation.

If you have any queries, please do not hesitate to contact me.

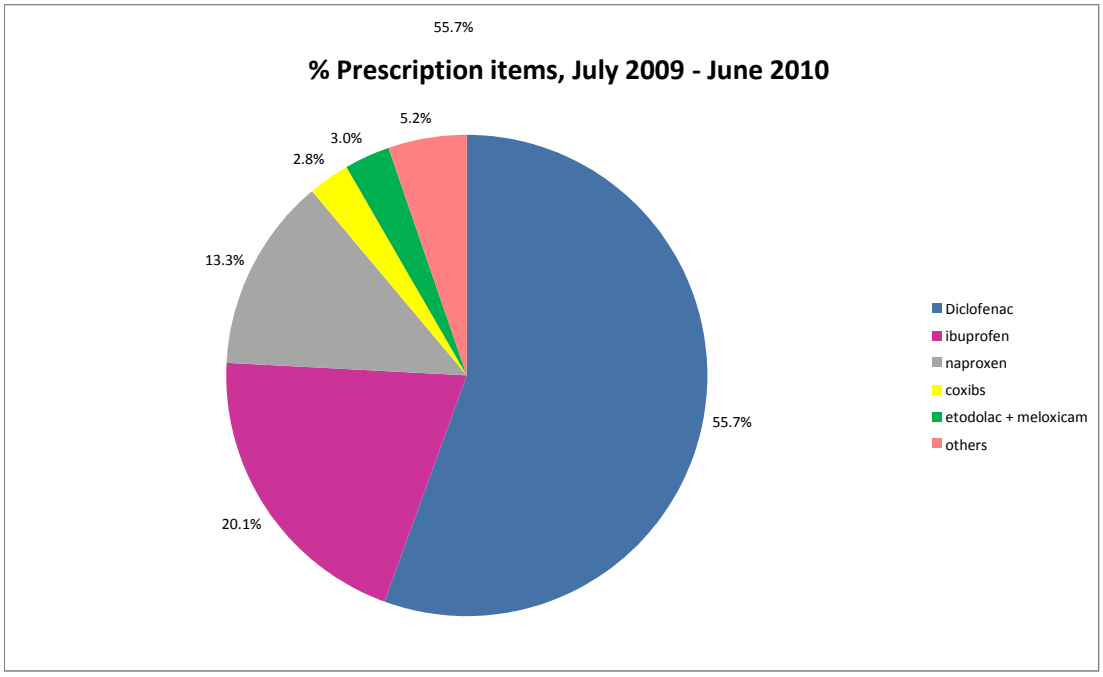
Kind regards,

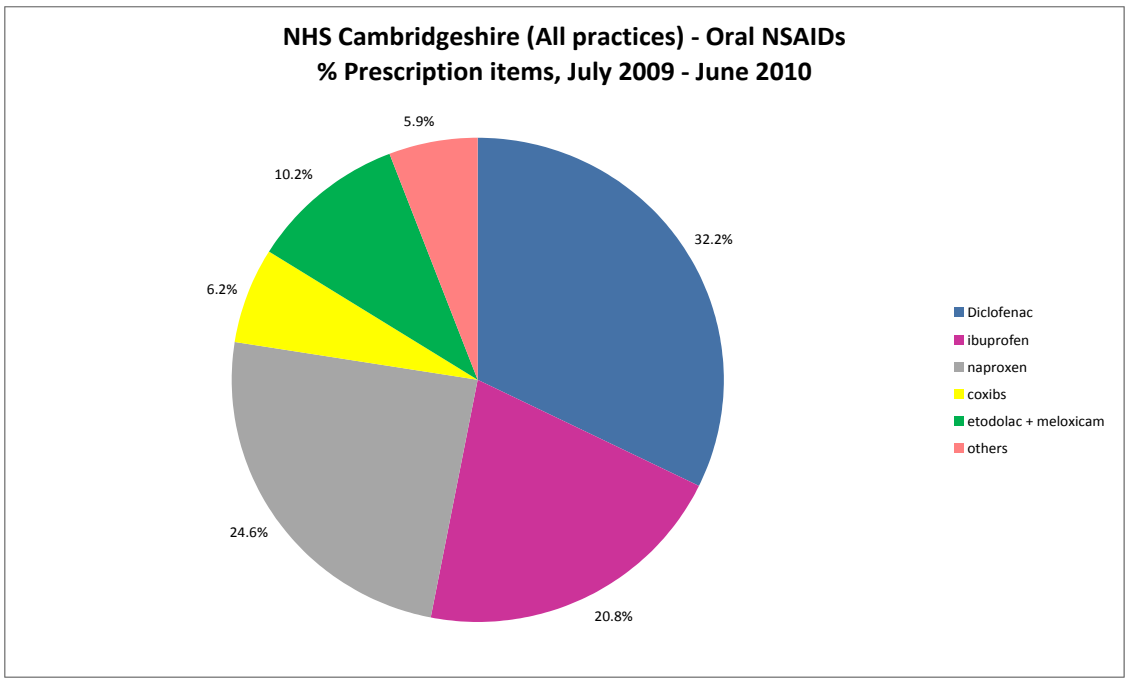
Melanie Whittick BSc, MSc, MRPharmS
Consultant Pharmacist

Cc: Practice Manager

Appendix 25

Example of Baseline Pie Charts and Accompanying Data





Dr ** & Partners
**** Health Centre**

Baseline

July 2009 – June 2010

	Practice				**PCT Average**				**Variation from PCT Average**		
	% Items	**% Cost**	**% ADQ**		**% Items**	**% Cost**	**% ADQ**		**% Items**	**% Cost**	**% ADQ**
DRUG GROUP - BNF chapter											
Muscoskeletal											
10.1.1 NSAIDs											
Diclofenac	55.7%	40.2%	59.1%		32.2%	23.1%	34.8%		23.5%	17.1%	24.3%
Ibuprofen	20.1%	9.7%	14.5%		20.8%	7.9%	14.8%		- 0.8%	1.8%	- 0.3%
Naproxen	13.3%	11.9%	14.2%		24.6%	17.5%	22.9%		-11.3%	- 5.6%	- 8.7%
Coxibs	2.8%	17.1%	3.0%		6.2%	28.0%	7.9%		- 3.4%	-10.9%	- 4.9%
Etodolac + meloxicam	3.0%	13.2%	4.2%		10.2%	15.2%	14.2%		- 7.2%	- 2.0%	-10.0%
Others	5.2%	7.9%	4.9%		5.9%	8.2%	5.4%		- 0.7%	- 0.3%	0.5%
Total	100.0%	100.0%	100.0%		100.0%	100.0%	100.0%				
MR NSAIDs / Oral NSAIDs	Practice	23.5%			PCT	29.1%					
10.3.2 Topical NSAIDs	Practice	21.9%			PCT	20.6%					

Appendix 26

Visit Summary Example (Anonymised)

**** Practice – Visit Four ** 08.11**

Summary of Previous Visit Report

Actions from Previous Meeting:

- The partners had agreed to check the practice database and review patients with diclofenac on repeat.
- The partners had received prescribing data before the previous meeting to establish whether the change in prescribing habits which had been agreed to implement had happened.

Actions for next meeting:

- Review how the prescribing had changed for both NSAIDs and anti-diabetic agents. Provision of ePACT trend data. (NSAID report already sent to GPs)
- Agree main focus of next meeting with GP lead. Topics to be finalised to meet practice objectives and needs.

Information required for Practice

- Provision of ePACT trend data on drugs used in T2DM.
- Provision of ePACT trend data on NSAIDs.

Prescribing Data Included for Visit 4

Summary of Prescribing Trends for NSAIDs and drugs in T2DM over study period.

This information has been updated with Data to May 2011

The partners had indicated that prescribing practice has changed and naproxen or ibuprofen is now used in preference to diclofenac in acute conditions.

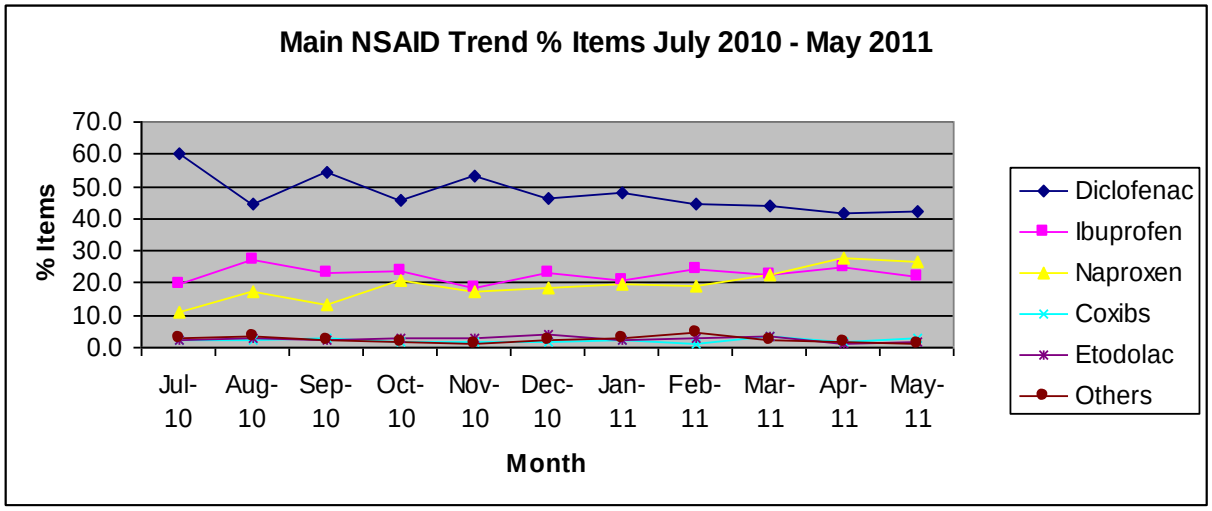
Trend Data

	No. Items										
	Jul-10	**Aug-10**	**Sep-10**	**Oct-10**	**Nov-10**	**Dec-10**	**Jan-11**	**Feb-11**	**Mar-11**	**Apr-11**	**May-11**
Diclofenac	136	97	123	86	117	92	93	102	96	97	91
Ibuprofen	44	59	53	45	41	46	40	55	50	58	47
Naproxen	25	38	30	39	38	37	38	43	49	65	57
Coxibs	5	5	7	3	4	3	5	3	7	4	6
Etodolac	5	6	5	5	6	8	4	6	7	3	4
Others	6	8	5	3	3	5	6	10	5	4	3
Mefenamic Acid	5	4	4	7	12	9	8	9	5	3	8
Total	226	217	227	188	221	200	194	228	219	234	216

Table 2. Prescription Main NSAID Items (Monthly) July 2010 to May 2011

	% Items										
	Jul-10	**Aug-10**	**Sep-10**	**Oct-10**	**Nov-10**	**Dec-10**	**Jan-11**	**Feb-11**	**Mar-11**	**Apr-11**	**May-11**
Diclofenac	60.2	44.7	54.2	45.7	52.9	46.0	47.9	44.7	43.8	41.5	42.1
Ibuprofen	19.5	27.2	23.3	23.9	18.6	23.0	20.6	24.1	22.8	24.8	21.8
Naproxen	11.1	17.5	13.2	20.7	17.2	18.5	19.6	18.9	22.4	27.8	26.4
Coxibs	2.2	2.3	3.1	1.6	1.8	1.5	2.6	1.3	3.2	1.7	2.8
Etodolac	2.2	2.8	2.2	2.7	2.7	4.0	2.1	2.6	3.2	1.3	1.9
Others	2.7	3.7	2.2	1.6	1.4	2.5	3.1	4.4	2.3	1.7	1.4
Mefenamic Acid	2.2	1.8	1.8	3.7	5.4	4.5	4.1	3.9	2.3	1.3	3.7
Total	100	100	100	100	100	100	100	100	100	100	100

Table 3. % Prescription Main NSAID Items (Monthly) July 2010 to May 2011



Graph 1. Overall NSAID Trend - % prescription NSAID Items April 2010 – May 2011

The trend data suggests that overall

- The decrease in diclofenac prescribing continues and is now levelling off
- There is a continued increase in ibuprofen and naproxen since baseline.

Summary

The updated data is based on currently available ePACT data to May 2011.
The data indicates that the anticipated trends based on change in NSAID prescribing choice by the GPs continues.

There is a reduction in diclofenac with a corresponding increase in naproxen and a small increase in ibuprofen.

Updated information can be made available as more ePACT data becomes available.

Further actions for Visit 4 - Suggestions

- Discuss prescribing data for NSAIDs and fact that GP actions are resulting in change in prescribing NSAIDs.

T2DM

Prescribing Data

- **Table 1. Prescription Items (Monthly) April 2010 to May 2011**
- **Table 2. Summary Main Prescription Items (Monthly) April 2010 - May 2011**
- **Table 3. % Prescription Items (Monthly) April 2010 to May 2011**
- **Graph 1. Diabetes Drugs Trend - % Prescription Items**

These tables and graph demonstrate the prescribing trends over 14 months for OHA items prescribed and percentage of overall OHAs. The data demonstrates that prescribing of metformin, sulphonylureas and glitazones has remained relatively stable during the timescale covered.

The practice has not generally prescribed any of the following:
- Combination metformin / glitazone products
- Newer drugs in diabetes
    - Exenatide, liraglutide
    - Gliptins

NB: In addition to a single prescription for sitagliptin in December 2010, a further prescription has been dispensed in April 2011. ? Regular patient on gliptin

The data demonstrates compliance with local recommendations around the newer drugs in diabetes and clinical recommendation not to use combination products which limit ability to titrate metformin. It is relatively unusual in practices and demonstrates a clear approach to the use of medication in the management of T2DM adopted by the whole practice.

There are a few regular prescriptions for glibenclamide and the partners may wish to review these patients and consider a shorter acting sulphonylurea.

Table 4. Glitazone Prescription % Items April 2010 to May 2011
Graph 4. Glitazone Trend - % prescription Items (Data from Table 4)

This data and graph show generally stable prescribing of glitazones although suggest that there may be an increasing trend in usage.

Further actions for next meeting - Suggestions

General discussion regarding data – Positive feedback!

Are there any areas of T2DM prescribing that the partners wish to address?

Are there any aspects of care that the partners would like to address?

eg Discussion around management of BP and lipids, ACE-I vs A-II-A, renal care, neuropathic pain.

Type 2 Diabetes

Trend data

	Items													
BNF Name	**Apr-10**	**May-10**	**Jun-10**	**Jul-10**	**Aug-10**	**Sep-10**	**Oct-10**	**Nov-10**	**Dec-10**	**Jan-11**	**Feb-11**	**Mar-11**	**Apr-11**	**May-11**
Acarbose	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Exenatide	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glibenclamide	0	5	1	4	3	2	4	3	3	2	2	2	4	4
Gliclazide	53	65	61	60	57	63	55	60	61	51	53	63	54	65
Glimepiride	2	3	1	2	0	3	0	3	1	2	0	3	0	3
Glipizide	2	1	0	1	1	0	1	0	2	0	0	0	1	1
Liraglutide	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Metformin	160	182	176	182	159	189	175	164	186	182	150	200	170	185
Metformin/Pioglitazone	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Metformin/Rosiglitazone	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Metformin/Sitagliptin	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Metformin/Vildagliptin	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nateglinide	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pioglitazone	21	15	21	18	13	24	22	26	23	27	19	29	30	25
Repaglinide	1	2	1	1	0	1	1	1	1	2	0	1	1	2
Rosiglitazone	3	5	4	2	4	2	0	0	0	0	0	0	0	0
Saxagliptin	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sitagliptin	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Tolbutamide	14	21	28	21	14	19	16	16	19	13	19	22	13	15
Vildagliptin	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	256	299	293	291	251	303	274	273	298	279	243	320	274	300

Table 1. Prescription Items (Monthly) April 2010 to May 2011

	Items													
BNF Name	**Apr-10**	**May-10**	**Jun-10**	**Jul-10**	**Aug-10**	**Sep-10**	**Oct-10**	**Nov-10**	**Dec-10**	**Jan-11**	**Feb-11**	**Mar-11**	**Apr-11**	**May-11**
Sulphonylureas	71	95	91	88	75	87	76	82	86	68	74	90	72	88
Metformin	160	182	176	182	159	189	175	164	186	182	150	200	170	185
Metformin/Pioglitazone	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Pioglitazone	21	15	21	18	13	24	22	26	23	27	19	29	30	25
Repaglinide	1	2	1	1	0	1	1	1	1	2	0	1	1	2
Rosiglitazone	3	5	4	2	4	2	0	0	0	0	0	0	0	0
Sitagliptin	0	0	0	0	0	0	0	0	1	0	0	0	1	0
	256	299	293	291	251	303	274	273	298	279	243	320	274	300

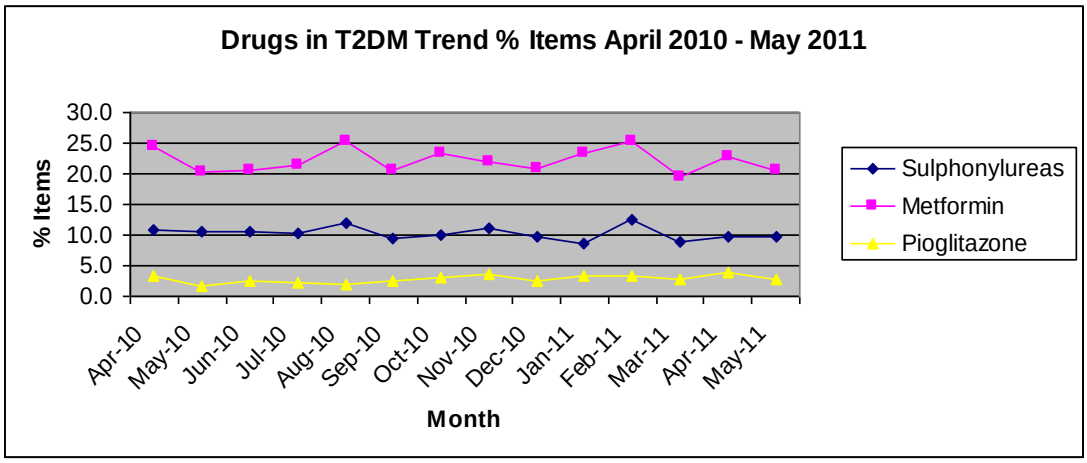
Table 2. Summary Main Prescription Items (Monthly) April 2010 to May 2011

	% Items													
BNF Name	**Apr-10**	**May-10**	**Jun-10**	**Jul-10**	**Aug-10**	**Sep-10**	**Oct-10**	**Nov-10**	**Dec-10**	**Jan-11**	**Feb-11**	**Mar-11**	**Apr-11**	**May-11**
Sulphonylureas	27.7	31.8	31.1	30.2	29.9	28.7	27.7	30.0	28.9	24.4	30.5	28.1	26.3	29.3
Metformin	62.5	60.9	60.1	62.5	63.3	62.4	63.9	60.1	62.4	65.2	61.7	62.5	62.0	61.7
Metformin/Pioglitazone	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0
Pioglitazone	8.2	5.0	7.2	6.2	5.2	7.9	8.0	9.5	7.7	9.7	7.8	9.1	10.9	8.3
Repaglinide	0.4	0.7	0.3	0.3	0.0	0.3	0.4	0.4	0.3	0.7	0.0	0.3	0.4	0.7
Rosiglitazone	1.2	1.7	1.4	0.7	1.6	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Sitagliptin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.4	0.0
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

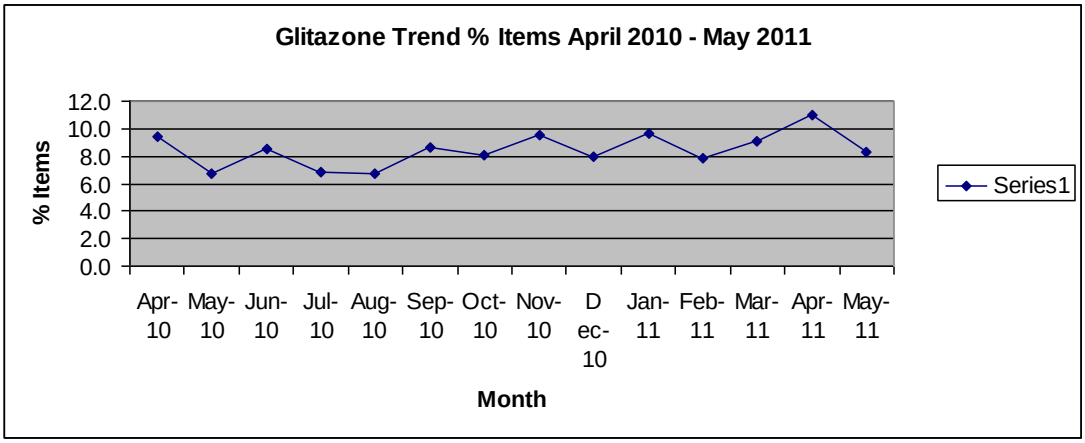
Table 3. % Prescription Items (Monthly) April 2010 to May 2011

	Apr 10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Oct-10	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11
Pioglitazone	8.2	5.0	7.2	6.2	5.2	7.9	8.0	9.5	8.0	9.7	7.8	9.1	10.9	8.3
Rosiglitazone	1.2	1.7	1.4	0.7	1.6	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Table 4. Glitazone Prescription % Items April 2010 to May 2011



Graph 2. Diabetes Drugs Trend - % Prescription Items



Graph 3. Glitazone Trend (All) - % prescription Items April 2010 to May 2011

Appendix 27

Study Specific Reference Documents

An individual folder was prepared for each pharmacist containing core study reference materials.

These included copies of:
- T2DM Academic Detail Matrix
- NSAIDs Academic Detail Matrix
- Table of Outcome Measures (ePACT and practice patient orientated outcomes)
- Powerpoint Presentation from Academic Detailing Revision Session
- NAO Report: Influencing Prescribing Cost and Quality in Primary Care

Evidence Based Reference Sources

Pharmacist Folders

Individual pharmacist folders contained key references for each therapeutic topic.

The key references included:
- Mandatory literature identified in the Detail Aid Matrices
- NICE guidance,
- MeReC publications
    - In particular pre-appraised summaries focusing on management of T2DM and NSAIDs
- Additional copies of pre-appraised summaries for distribution to GPs if required during the practice visits were also included in each folder.
- Copies of Detail Aids

Central 'Library'

A central repository containing key references, and supporting evidence based information was maintained by the Chief Investigator. Its purpose was to:

- Facilitate pharmacist access to information to support knowledge and learning objectives around the evidence base and key messages.
- Provide support materials in anticipation of questions and requests for evidence based reference sources as a result of discussion with GPs (including original references).

The central repository also included copies of:
- Therapeutics and Information Mastery training slides
- NPC key slides and data focussed commentaries.
- National Guidelines (including NICE) e.g. T2DM, Management of hypertension, management of renal insufficiency
- Original references

Appendix 28

Visit Report Examples (Anonymised)

Practice Visit ** Surgery ** May 2011

Present:

Dr **, GP, Senior Partner	**, Nurse Practitioner
Dr **, GP	**, Practice Nurse
Dr **, GP, Prescribing Lead	**, Pharmacist (MMT)

Purpose of the Visit

This was the second study visit as part of a research study evaluating the impact of prescribing support/advice on GP prescribing behaviour. The study topics are focussing on two aspects of care, NSAIDs and management of T2DM.

Recap

T2DM. The baseline visit focussed on management of various aspects of T2DM and the evidence behind recommendations around approach to management.

The group had discussed prioritisation of treatments in managing T2DM and cardiovascular risk utilising the 'diabetes hand' approach. 'Pharmacist' reviewed the evidence from UKPDS relating to management of blood pressure and blood glucose and the importance of metformin in reducing CV risk. Pharmacist used PDAs to demonstrate relative benefits of the different interventions in UKPDS.

The group discussed the more recent evidence for use of aspirin in primary prevention and for sequence of antihypertensive choice in the management of hypertension.

There was some discussion on the use of oral hypoglycaemic agents (glitazones) and the newer drugs in diabetes. The practice had relatively high use of metformin combination products and this was an area where they may consider preferential use of the individual drugs.

The focus of this meeting was also on aspects of care in T2DM as agreed with Dr 3 (PL). Pharmacist had also brought some trend data on prescribing of NSAIDs which had not been discussed at the previous meeting.

NSAIDs

- Diclofenac and coxibs are associated with higher CV risk than other NSAIDs. Low dose ibuprofen and naproxen are associated with lower thrombotic risk.
- All NSAIDs carry risk of GI side effects
- When prescribing NSAIDS it is important to assess cardiovascular, cardiorenal and GI risk according to individual patient factors.
- Baseline data (pie charts) indicate that as a practice, prescribing of diclofenac is lower than the PCT averages which is appropriate in order to limit / reduce diclofenac associated CV risk.
- Use of COX-II inhibitors is slightly higher than PCT average and this may be an area for the partners to consider in the future.
- The group discussed the fact that both CV and GI risk are cumulative, increasing with length of treatment and dose.
- The partners recommend NSAIDs on a p.r.n. basis where possible
- The NICE recommended approach to management of musculoskeletal disorders was reviewed. In addition to core treatments, first line therapeutic options are paracetamol and topical NSAIDs.
- CPCT formulary suggests ketoprofen as a first line topical preparation (based on cost effectiveness). Ketoprofen is also more potent than other options. The partners are aware that ketoprofen is associated with a higher risk of photosensitivity about which there are concerns. Therefore other first line options may be more appropriate.

- The partners were reminded that topical application of NSAIDs (particularly large amounts) may result in systemic side effects eg asthma.
- The practice has a template in place on its computer system which considers risk associated with prescribing of NSAIDs.
- Dr 1 considered that review of patients on long term diclofenac might be an appropriate subject for one of the practice quality projects. To consider associated risks eg CVD, CKD, GI and concomitant use of other drugs which can exacerbate adverse events eg SSRIs and GI bleeds. Pharmacist is happy to provide support the practice where appropriate.

Action GPs, PNs

T2DM

Previous discussion with Dr 3 suggested focus of meeting on
- New diabetes drugs
- ACE-I vs A2RA (particularly re. proven benefits of ACE-I)
- BP control in CKD (focus on T2DM)

Aspirin
- Pharmacist had brought a number of evidence based updates questioning the use of aspirin for primary prevention in T2DM as an action from the previous visit. This included summary details from POPADAD and recent meta-analysis (six studies).
- There was further discussion on the lack of evidence for the benefit of aspirin in primary prevention. A key factor is the fact that benefit of reduction in CV risk needs to be balanced against the increased risk of a major bleed.
- The more recent evidence contradicts the current NICE guidance recommendation to prescribe for patients over 50 years (with BP <145/90mmHg)
- Currently patients with T2DM (primary prevention) are having aspirin actively stopped by the GPs.
- In some cases it may be appropriate to consider prescribing aspirin depending on the patients individual risk factors. If aspirin is prescribed, it is important to ensure BP is controlled.
- Pharmacist also brought copies of the Antiplatelet PDAs on aspirin for primary prevention of cardiovascular disease for the GPs and PNs to review and use when discussing with patients if appropriate.
- A copy of the whole NPC PDA folder had been left previously with the practice.

Drugs in T2DM
- Prescribing trend data shows no prescribing of the newer drugs exenatide, liraglutide. There appears to be one recent repeat for sitagliptin.
- The practice is relatively high prescriber of metformin (reduces CV risk).
- Overall use of glitazones is below PCT average and has decreased recently.
- Since baseline, use of metformin combination products has virtually ceased.
- GP1 tends to be more cautious in use of glitazones in view of continuing concerns and adverse effects attributable to glitazones.
- There is currently less experience with the use of gliptins.
- Sequence of antihypertensive following ACE-I was briefly discussed. Although either thiazide or CCB are recommended as second line add in options, there is strong evidence that a thiazide is an appropriate and cost effective second choice. (ALLHAT Study). NB: does not cause ankle oedema.

Renin-Angiotensin Drugs

Pharmacist had agreed with GP 3 (prescribing lead) to cover the evidence relating to use of RAS drugs ie ACE-Inhibitors and Angiotensin Antagonists.
- Current NICE guidance advocates use of RAS drugs in
    - Hypertension
    - Heart failure
    - Post MI

    - T2DM
    - CKD
- For each of these indications NICE recommends ACE-Is first line where RAS drugs are recommended.
- A2RAs should be reserved for patients where ACE-Is have to be discontinued because of intractable cough. (A2RAs cause less cough than ACE-I)
- There is no evidence that A2RAs are superior to ACE-I in any indication
- There is no evidence that A2RAs are safer than ACE-I in any indication
- Incidence of cough may be less than generally thought
  Evidence from ONTARGET,
    - Incidence of cough 4.2% (ramipriil) vs 1.1% (telmisartan)
    - Absolute difference 3.1% (possibly underestimate but not high as thought)

Combination therapy with ACE-I and A2RA.

- No more effective than either treatment alone (ONTARGET study)
- Associated with more discontinuations due to hypotension, syncope, diarrhoea and renal impairment
- There is considerable concern regarding renal deterioration with combination
- The combination is not recommended except by specialists (renal care)
- Bottom line
    - Hypertension – No benefit, worse outcomes
    - Renal disease – No benefit, worse outcomes
        - If specialist using in minority of patients with proteinuria not responding to monotherapy, requires very careful monitoring
    - Post MI - Not recommended
    - Heart Failure – Possible specialist option. However, concerns regarding renal failure. Requires very careful monitoring.

General

- Dr 2 asked about use of Calcium and Vitamin D in combination for patients with Vitamin D deficiency (eg elderly, inflammatory conditions, anaemia). Are there implications associated with possibly too much calcium eg increased CV risk in using the available preparations. Pharmacist will investigate and feed back.

Action: Pharmacist

There was not enough time to cover all of the topics previously discussed with Dr ** (PL) Eg New drugs for management of blood glucose.

As the second visit had been postponed, the option of carrying out one further visit or whether to squeeze two further visits was discussed. It was agreed to complete two more shorter visits as part of the next two practice nurse meetings.
Dates of next meetings:

** June 2011 12.30pm
** July 2011 12.30pm

Pharmacist to confirm focus of meeting with Dr 3, Practice Lead prior to the next visit.

Practice Visit ** Medical Practice Date: ** February 2011

Present:
Dr 1, Dr 2
Pharmacist, MMT

Introduction

The pharmacist summarised the purpose of the visit (2nd) and how it related to the research study which is to evaluate the impact of prescribing support /advice on GP prescribing behaviour it is intended to follow up the baseline visit with further visits. Prescribing data will be used to examine to assess change in prescribing patterns in the use of anti-diabetic medicines and NSAIDs. Two further meetings would follow during the year to re-enforce the messages relating to NSAID and diabetes prescribing, and to feedback on prescribing trends.

Topic	Discussion points	Actions
Prescribing NSAIDs	• Pharmacist confirmed how the use of non-pharmacological approaches such as weight management and exercises would be considered first, and use of paracetamol and topical NSAIDs as the first step pharmacological treatment for the management of osteoarthritis • Pharmacist revisited previous discussed area: GI related risks and the use of NSAIDs, and stated that patients that are over 65 years old, with a history of GI problems such as bleeding and ulceration would be at high risk of GI side effects relating to the use of NSAIDs • From the data available for the first meeting it was noted that the practice were high users of naproxen. • Pharmacist presented the previously shared epact data. The practice at November were prescribing 32.2% diclofenac items, 17% Ibuprofen, 36% naproxen, 2.9% Coxibs and 5.9% Etodolac and Meloxicam. The practice would like to become a higher user of Naproxen, and has agreed to review patients currently on Diclofenac with a view to switch patients to Naproxen if appropriate. • The pharmacist commented that the Practice has a higher than PCT average use of Naproxen (12.6% higher than PCT average), which is commendable. • As previously discussed, Coxibs and Diclofenac exhibited similar CVD risk profile in causing an extra 3 CVD events per 1000 patients per year. There are no direct risk data for Meloxicam, but the PCT do not advocate it's use. Pharmacist shared that Meloxicam may have a similar CVD risk profile, but there are not data at hand to demonstrate this. There is also weaker evidence to support its use. • The practice requested further practice data on the prescribing of NSAIDs, relating to patient number and their current renal status. • Discussed 2 trials, MELISSA and SELECT and the lack of evidence to support the use of meloxicam. For Melissa, there was no significant difference between the groups in the occurrence of perforations, ulcers or bleeds (five patients with meloxicam and seven with diclofenac), but the study was only short-term and was not powered to show this. • The practice has agreed that reviewing Meloxicam could be a further action point, e.g. at visit three. The GPs felt that the use of Meloxicam is mainly secondary care led. • Pharmacist re-asserted the importance of risk assessment	Review patients on Diclofenac, stop and switch to ibuprofen or Naproxen if appropriate.

	and how GI protection is important for patients using a PPI when necessary if the use of a NSAID cannot be avoided	
Type 2 diabetes (general)	• Pharmacist discussed again the importance of managing CVD risks in type 2 diabetic patients, by showing that that 63% of diabetic patients died from CV causes, which is twice the percentage of normal population (33% of non-diabetic patients died of CV causes) • As per discussion at the last practice visit, the practice is currently managing its diabetic patients using QOF indicators and are achieving good results according to QOF requirements, this include BP control in diabetic patients • Pharmacist discussed that the cornerstone of evidence in managing type two diabetic is the UKPDS study, which shows that managing patients BP and using metformin were associated with much better outcomes for patients • Pharmacist revisited the use of the 'Diabetic Hand' in the management of type two diabetic patients. Both GPs remembered the points well. • The practice is currently exhibiting 'clean' data for the prescribing for type two diabetic medications. 66.2% on Metformin, which is 11% higher than PCT average, 32.3% patients on Gliclazide. The practice has discontinued the only one patient prescribed a gliptin and has make changes to all patients prescribed Rosiglitazone to an appropriate agent. Pharmacist commented that Glitazones and Gliptins should be third line treatments. • Pharmacist confirmed that all diabetics should be using ACE inhibitors across all ages due to better evidence in preventing cardiovascular events. Pharmacist also mentioned a recent BMJ meta-analysis that showed that A2RAs has no evidence in preventing stroke when compared to placebo • Pharmacist showed the scatter plot of Law and Morris et al 1999, and explained that there is no evidence of AII in preventing stroke and much weaker evidence in the prevention of cardiovascular events. • Pharmacist also demonstrated using the same graph that prescribing of beta blockers causes excess risk in causing stroke, hence this is not recommended in NICE guidance. • Pharmacist showed data collated by CI, and showed that there was a patient being prescribed two calcium channel blockers. Dr. ** will review the patient. • Pharmacist discussed that simvastatin 40mg remains to be the first line treatment for controlling cholesterol levels even in type two diabetic patients with CVD risk of >20%. • The practice observed from the practice data that 8 patients with microalbuminuria not prescribed an angiotensin drug, the practice has agreed to review these patients and treat appropriately. • The practice also noted that 19 patients on AII, and has agreed to check if these patients were prescribed ACE as a first line agent. • The practice was provided with the printed spreadsheet with patients renal status and medication histories.	The practice will review all type two diabetics on AIIs and check if ACE are used first line in managing BP Review of the patient being prescribed two CCBs Review 8 patients with microalbuminuria not prescribed an angiotensin agent. To review patients on AII (19) and assess if patients were prescribed an ACE prior to AIIs.
Newer Diabetic drugs	• The practice is aware of current process of requesting consultant opinion prior to the initiation of gliptins and the process of delegating prescribing of Exanetide to primary care.	

	• The practice is reminded that all relevant paperwork can be accessed via the CJPG website • The practice is not aware of any difficulties or problems to date. • Pharmacist showed that the HbA1c lowering power of newer diabetic drugs are not as potent as Metformin and Gliclazide, 0.5-1.5% for Glitazones, up to 0.7% for Gliptins and up to 1% for Exanetide. Both Metformin and Gliclazide could lower HBA1c to up to 2%.	
	The meeting was closed and then all four actions reviewed.	

Feedback from Practice Visit 2
**** Practice Date: ** December (30 minutes)**

Present:
GPs – Dr 1, Dr 2, Dr 3, Dr 4, Dr 5, Dr 6, Dr 7
Practice Nurse (Diabetes)
Pharmacist, PCT Medicines Management Team

Topic	Discussion points	Action for next meeting
Introduction	• Pharmacist reminded GPs of the research project – effect of 4 visits by pharmaceutical adviser to be assessed (on 2 subject areas- type 2 diabetes/NSAIDs) spread over 1 year • At the previous visit, the practice had expressed interest in comparisons with neighbouring practice (NPS) where the population was deemed "similar" to this practice. Pharmacist produced comparative data on both NSAIDs and diabetes treatments. NP Surgery had agreed to share with this practice and, and GPs present also indicated willingness for data to be shared with NPS. 'Electronic link to Word document containing comparative data inserted here' • The practice had also suggested that deprivation played a part. Pharmacist confirmed prevalence is definitely higher than average (LISI deprivation weighting 9.3 compared to PCT average 6.2). • GPs had previously asked if new Medicines Management Solutions Audit tool would help identify which GP in a practice had initiated a treatment. GP4 had found that it would. Pharmacist had no further information as to whether this tool was to be implemented.	• Pharmacist to send comparative data to NP Surgery for information.
Diabetes prescribing data	• Comparative data with NPS showed both practices had higher-than-average prescribing rates for oral antidiabetic drugs, metformin, insulin and blood glucose test strips (BGTS).	

Topic	Discussion points	Action for next meeting
Blood Glucose Testing Strips (BGTS)	• Higher-than-average prescribing of BGTS was found to correlate with higher-than-average insulin costs, but NPS insulin costs were higher than Practice (with lower BGTS costs). Unclear whether this might be due to particularly expensive forms of insulin used at NP, or inappropriately low testing of BG at that practice. GPs confident that testing at this practice is only undertaken if appropriate. • Pharmacist provided trend data for prescribing of BGTS. This did show the work the practice had put in to reduce prescribing, but also showed a subsequent rise again. 'Electronic link to Excel document containing prescribing trend data inserted here' • Practice felt that remaining prescribing was probably appropriate (considerable input already from medicines management team on this topic). • GPs suggested it would be helpful to compare numbers of patients instead of costs.	• Pharmacist to investigate data further, to find whether type of insulin or volume was influencing high costs at NPS. • Pharmacist to ask NPS surgery if they can supply patient numbers for insulin and sulphonylureas
Insulin Mixtard	• Practice aware that this was to be discontinued shortly. • All 18 patients to be reviewed and changed by Diabetes Specialist Nurse. (Patients have sufficient Mixtard to last until the change-over effected).	
Glitazones	• Pharmacist confirmed latest data (September 2010) still showed 17 prescriptions for rosiglitazone issued. • Practice staff were confident that October data would show zero. (Patients would not have been able to accumulate prescriptions to obtain supplies after the withdrawal of rosiglitazone.)	• Pharmacist to check later data to ensure rosiglitazone prescribing stopped.
Exenatide	• Pharmacist advised new guidance on exenatide was imminent. • Consultants would retain prescribing for 6 months, at the end of which period, the patient would be assessed for compliance with NICE criteria for continuing treatment (required weight loss and HbA1C change). If continuing treatment appropriate, consultant to write to GP with details, and GP to continue. • Patients started on treatment to be given a leaflet explaining that treatment will be stopped if NICE criteria not met. • Pharmacist confirmed practice would need to monitor to ensure weight loss etc maintained	
Gliptins	• Pharmacist advised new guidance on gliptins was imminent. • GP would need to contact consultants before prescribing – patient to be seen as outpatient or GP to telephone consultant to discuss. DH confirmed cost of telephone consultation would be lower than cost of out-patient appointment. • If consultant agreeable, GP can initiate. (Contact must be between GP and consultant – not diabetes specialist nurses). • Checklist of information will be provided to GPs. • Patients started on treatment to be given a leaflet explaining that treatment will be stopped if NICE criteria not met.	

Topic	Discussion points	Action for next meeting
Aspirin in diabetics	• Pharmacist had researched current guidance on use of aspirin in diabetics. • Aspirin is still recommended in secondary prevention patients (existing CV disease). Practice confirmed these are still being prescribed. • Advised that, for primary prevention, latest guidance from NPCi suggested that, in all age groups, this was no longer routinely recommended (but that it might be appropriate to continue in patients where cardiovascular risk deemed to be particularly high in a primary prevention patient) – see http://www.npci.org.uk/blog/?p=995 . • Practice had taken all patients under the age of 50 off aspirin if primary prevention, but was still prescribing for over 50's. All agreed probably appropriate now to review these individually (but concerned about workload). Pharmacist suggested that it might be more manageable to flag the notes to ensure use of aspirin reviewed at annual/6-month review in practice (i.e. at a scheduled appointment). This would stagger workload. • Discussed use of CV risk tool – GPs tend to use QRISK assessment for diabetics (as available on computer system). Pharmacist not sure whether QRISK accounted fully for the risk from diabetes, and suggested UKPDS assessment tool might be more appropriate. • Unclear whether there might be a code for using the UKPDS tool in the computer system.	• GP 4 to check numbers of primary prevention diabetics still prescribed aspirin. • Practice to check results obtained with QRISK template against that obtained with the UKPDS template. (Available from UKPDS website – see http://www.dtu.ox.ac.uk/riskengine/index.php)
NSAIDs	• Briefly noted that the comparative data with NP Surgery did not appear to correlate with that from Practice (NSAIDs prescribed per patient in Practice appeared higher-than-average, but lower-than-average in NP Surgery). • Due to shortage of time, discussion of the data (and follow-up on NSAID points from last meeting) deferred to next session.	• Pharmacist to bring data again to discuss at next meeting. • Pharmacist to bring forward follow-up NSAID points to next meeting.
Topic	**Discussion points**	**Action for next meeting**
Next meeting	• Date to be booked as soon as possible. • To cover topics highlighted above, and any other related issues that arise in the meantime.	• Pharmacist to arrange new date with specified GP and/or Practice Lead

File ref: R:\Pharmaceutical\ ** \visit2.doc

Appendix 29

Review of Baseline Visits - Meeting 4th November 2010
Agenda / Discussion Points

1. Baseline Visits.
- Experiences so far
- Analysis and interpretation of the data to steer conversation and influence prescribing at each meeting.
- Use of Detailing / Educational Outreach Techniques
- Background Information / Training
    - NPC
    - NAO Report
    - Presentation
    - Detailing: Planning Matrix / Key Messages
    - Outcomes being measured
- Presentation Materials – Detail Aids
  Folders, Sticks, Data, Information
- Support Materials

2. Summary of Visit Reports

3. Visit Reports
- Visit Report Format
- Visit Report Timeframe Within 1 week **Maximum 2 weeks**
- Agreed Actions
  Timeframe – Agree with Practice
  SMART
  Provision of additional information eg clinical, ePACT

5. ePACT Data
- Provision of ePACT data following visit as result of agreed actions
- Use of additional graphs for the practice visits
- Preparation?
- Preparation of data for next round of visits

6. Detail from outcome data to inform visits?

7. Follow up visits
- Booking Next Visits ASAP ie First follow up
- Arrangements to determine
  content , structure, attendance
  Information requirements for next round of visits

Suggest - Contact practice in advance of following visit to discuss

8. Sharing Information
Clinical
Experiences

9. Housekeeping - Folders / files on system
Visit Reports
Data –
e-PACT Data – downloaded / graphs for visits / additional

Appendix 29 (Cont.)

Review of Baseline Visits - Meeting 4th November 2010

Discussion Points and Actions

1. Baseline Visits.

There was a general discussion of individual experiences so far

- Approach to visits –

- Use of Detailing / Educational Outreach Techniques
    - There is clearly a variation in approach which may be partly due to experience – As indicated earlier, it is important to use and develop the techniques we already have and learned.
    - MW summarised key points regarding academic detailing in a short presentation (attached).

- Presentation Materials – Detail Aids
    - Again, there is a range of approaches with some individuals using detail aids more than others
    - Some people are using it more as a formal presentation, others less so.
    - A number of visit reports are very similar, reflecting standard approach. Whilst it is accepted that the topics covered may be similar and overlap, it is important to utilise and develop the techniques we already have and have learned during training and re-iterating the detail aid messages.
    - A reminder, we can aim for consistency by focusing on the key messages and lead into the detail based on discussion with the GPs and nurses.

- Presentation Materials
    - Memory Sticks – General agreement that not particularly practical and may have possible time constraints.
    - Folders - Everyone generally comfortable with hard copies of detail aids. (Remember - A4 folder each and two A3 folders for those who prefer to use larger folder).

- Analysis and interpretation of the data to steer conversation and influence prescribing at each meeting
    - Did not discuss and obtain individual feedback regarding this point.
    - However, point made that some GPs are resistant to sharing their data. Please note that GPs can be reassured that data is confidential and not shared without agreement or is anonymised.

Background Information / Training

- MW reminded everyone that there is a considerable amount of background information which has been prepared and provided for the project which everyone should be familiar with. This ranges from information about the study such as to reference sources relating to detailing techniques and clinical references / resources intended to support the information presented in the detail aids.

MW reminded everyone about the NAO Report 'Influencing Prescribing Cost and Quality in Primary Care' which has previously been forwarded and circulated as a link and which contains a really useful summary of the practical application of detailing techniques and including planning, targeting and communication with clinicians. MW requested that please can everyone read the sections that she has highlighted previously. MW will also provide further copies of the protocol for pharmacists.

- In addition, everyone has been given a folder which contains:
    - Academic Detailing Planning Matrix for T2DM
    - Academic Detailing Planning Matrix for NSAIDs
    - Outcomes being monitored and measured for the study ie
        - Prescribing Data - ePACT
        - Outcome Data – Practice level

The detailing matrices provide details on the aims of the sessions, key messages, possible areas of controversy. Please can everyone ensure that they have familiarised themselves with these documents as they are intended to guide and support pharmacists in conducting the practice visits. They also contain the information which is intended to promote consistency when conducting the visits. Knowledge of the outcome measures should also help pharmacists focus on the required changes when directing discussions with the GPs.

- Support Materials
    - Additional materials include NPC training materials, references quoted on the slides including original references, MeReC summaries (eg RAS Drugs, NSAIDs). These are filed in a box in MW's office. So far not aware that these have been accessed although MW has used some of this information when responding to queries raised by other pharmacists resulting from practice visits. NB: Dealing with queries covered later in these notes.
    - Please note that there are copies of the current NICE guidance for T2DM and NSAIDs. There are enough copies for each GP in study practices and nurses. It was intended that the NICE guidance (and MeReCs for example) are available for distribution during/following practice visits.

2. Visit Reports

- Visit Report Format

    - In general, most pharmacists have adopted the study report format that ** had shared before the study visits started and this appears to be the preferred approach. As indicated earlier, it is acceptable for individuals to use the template or adapt to suit their style. It was confirmed that a standardised report format is not crucial. The most important aspect is to ensure that the discussion points from the visit are documented accurately, action points noted and feedback is provided to the practice in a timely manner.
    - There was some discussion on content of report. It is not intended that feedback is uniform (ie same content/actions for all practices). Not possible to be prescriptive about content. More that visit report and resulting actions reflects discussion topics addressed during individual visit.
    - There is a variation in timing of writing up and dissemination of feedback between pharmacists. It is most important to ensure that the visit and

discussion details are documented quickly so that accurate notes can be made. Agreed data and information requirements can be followed up accordingly.
    - SU suggested blocking time in the calendar immediately after practice visit to write up. This will require commitment to the process. It was agreed that this approach be implemented by all members of the study team in order to ensure consistency and timely feedback.
    - NB: If it is not possible to write up immediately after the visit, it is suggested that preliminary notes and actions at least are written up within two days to capture the main discussion points and actions. This could be in bullet form initially.
    - Visit Report Timeframe - Please stick to original request to feedback full report to practice preferably within one week, *maximum* two weeks.
    - Please forward copy of each visit report to MW

- Visit reports should document
    - Agreed Actions
    - Timeframe for Actions – Agree with Practice
    - SMART
    - Requirements for provision of additional information eg clinical, ePACT

- MW presented a summary of actions from the baseline visits disseminated so far to practices. Pharmacists are able to follow up queries with individual practices. Some of the actions resulting from different practice visits are similar. If pharmacists are struggling to follow up actions, where possible, MW will follow up the queries to support the other pharmacists particularly for clinical queries.
    - NB: Please d/w MW as soon as possible following visits if there are actions that she may be able to help other pharmacists with.

- MW will prepare a FAQ sheet from the visit reports. This will be accessible by everyone and will help reduce duplication of effort if similar queries are raised.

3. Visit Summaries

It has been requested that each pharmacist will provide a written feedback following each practice visit. To include personal experience, impressions, GP feedback etc.

4. Data

- Provision of ePACT data following visit as result of agreed actions
    - It was agreed that it is not appropriate to pull off the same data for the next round of visits as for the baseline visits. Because of the delay in ePACT data it will not be possible to provide comparative data to detect a difference at this stage.
    - Next set of routine data will need to be pulled off for third visits to feedback to GPs and detect whether any change in prescribing.

- Preparation of ePACT data for next round of visits - MW to address

- Preparation of additional data/graphs as a result of actions from practice visits
    - One pharmacist is pulling off her own additional data based on visit discussions. If other pharmacists are able to do this then this is fine as it will be tailored to the practice's needs.

- MW to negotiate for others. Please advise data requirement if you are not able to pull off information from agreed actions.

5. Outcome Data to Inform Visits?

- For information – The outcome data MW is collecting from practice searches is primarily intended to enable a before and after comparison to assess whether there has been an impact as a result of the intervention.
  - It was not originally intended to utilise the data within the practice visits. However, it has become apparent that some of the information collected at baseline might actually inform the discussions around prescribing and be useful in the communications with the partners. MW has already offered to share this information with one of her practices. One pharmacist had a query from PH Surgery for which MW's data may provide an answer.
  - From a practical perspective, the practices could extract the information themselves following on from discussions with the pharmacists. However, as the data is available MW is happy for pharmacists to share information with the practices if appropriate.
  - The type of data includes
    - proportions of patients on ACE-Is versus A-II-As
    - HbA1c levels
    - BP levels
    - Drugs prescribed for blood glucose lowering, BP
    - Patients on NSAIDs also on aspirin, PPIs, SSRIs plus much more
  - MW will provide details of data available and information which can be extracted from it. MW will feedback to other pharmacists.
  - Please ask Melanie if you think that any of this information will support pharmacists in delivering the intervention in individual practices.

7. Follow up visits

- Booking Next Visits MW will ask Sec to book the next visits which are due in December
  - MW and one other pharmacist will be contacting practices direct to set up the meetings. The other pharmacists may wish to consider this approach.

- Arrangements to determine content , structure, attendance, information requirements for next round of visits
  - MW is also planning to contact the GP prescribing lead / GP study contact to discuss and confirm the content of the next visits in advance of the visit. MW requested that this approach be considered by the other pharmacists. Ie Contact practice in advance of following visit to discuss. This may also help focus on visit content and aid preparation.

- It will be necessary to review individual actions prior to the next visit to ensure that they have been addressed.

- Topics for next meeting
  - Some individuals are not sure what topics to cover at the next meeting. Hence, review of actions and encouragement to contact PL in advance to tailor to practice requirements. (Direct communication will also promote engagement with the practice that we are trying to develop).

- If only one topic covered in baseline visit, other topic should be addressed in next visit (plus re-iteration of initial topic as appropriate).
- It is anticipated that by the time the next meeting is due, the PCT guidance on newer drugs should be available. This will be a hot issue and practices will be keen to find out what the requirements are. Therefore, suggest that this is a topic may be suggested to practices a as an option if pharmacists feel appropriate. Obviously it addresses PCT policy, however, the recommendations are essentially based on the evidence presented in the NICE guidance which is the subject of the detail aids.

8. Sharing Information

- It is really important that as a team working on the project together, we share information both
  - Clinical
  - Relating to experiences

Please can we keep each other informed and share information relation relating to the study and its progress, issues etc. – As we do in real practice.

- MW will prepare a FAQ sheet from the visit reports. This will be accessible by everyone and will help reduce duplication of effort if similar queries are raised.

9. Housekeeping - Folders / files on system

- The main study files are in a folder 'Project EBH.
  - Visit Reports
  - Practice Data
  - e-PACT Data – downloaded / graphs for visits / additional
  - Detail Aids
  - Additional Slides
  - Evidence

The folders are available for access and reference. (Please do not alter filed documents).

10. Miscellaneous

- COX-II Selectivity slide useful. To be shared and added to 'Additional Slides' folder in 'Detail Aids' folder in Study folder (Prescribing/Project EBP/Detail Aids)
- MW will prepare other additional slides as necessary and forward to everyone as well as filing in 'Additional Slides folder.

Appendix 30

Practice Searches – Data Collection Requirements Type 2 Diabetes

Search: Current Registered Practice Population with T2DM

Report: Practice T2DM population (eg Korner bands, capitation report) as proportion of current practice population.

Build up report containing data listed:

- Patient ID
- Age in years
- Gender M/F

- Current Blood Glucose Lowering Medication
    - Insulins
    - Metformin
    - Sulphonylureas and related drugs group
    - Rosiglitazone
    - Rosiglitazone and Metformin
    - Pioglitazone
    - Pioglitazone and Metformin
    - Repaglinide
    - Nateglinide
    - Acarbose
    - Sitagliptin
    - Vildagliptin
    - Saxagliptin
    - Exenatide
    - Liraglutide

NB: All but insulins, metformin and sulphonylureas may be also extracted under 'other' drugs used in diabetes

Latest recorded value:

• HbA1c	Previous 2 years	Latest, date and value
• SBP	Previous 2 years	Latest, date and value
• DBP	Previous 2 years	Latest, date and value
• Urine Albumin:Creatinine Ratio	Previous 2 years	Latest, date and value

- Current Antihypertensive Medication:

    - Thiazides and related diuretics
    - ß-blockers
    - α-blockers
    - CCBs
    - ACE-I
    - A-II-A
    - Vasodilators
    - Centrally Acting Antihypertensive

Appendix 30 (Cont.)

Practice Searches – Data Collection Requirements Type 2 Diabetes (Cont.)

- Current Aspirin / Antiplatelet

- Current Lipid Lowering Therapy (Drugs used to treat hyperlipidemia)

Latest recorded value

• Total (serum)cholesterol	Previous 2 years	Latest, date and value
• Serum LDL	Previous 2 years	Latest, date and value
• Serum TG	Previous 2 years	Latest, date and value

NB: Read Codes on Torex may be different from those on EMIS or System One

Appendix 31

Practice Searches – Data Collection Requirements
Non-Steroidal Anti-inflammatory Drugs

Search: Current Practice Population on NSAID (excluding Aspirin)

Report: Practice population on NSAID (eg Korner bands, capitation report) as proportion of current practice population.

Build up report containing data listed:

- Patient ID
- Age in years
- Gender M/F

- Repeat NSAID and Current NSAID (where possible) during previous 12 months

- Indication

- Present medication (in addition to NSAID)
    - Aspirin
    - PPI
    - SSRI

- Read Code for

○ Peptic Ulcer	J130	Latest
○ CKD 5	1z14	Latest
○ CKD 4	1z13	Latest
○ CKD 3	1z12	Latest
○ Heart Failure	G58	Latest
○ Hypertension	G20	Latest
○ Ischaemic Heart Disease G3		Latest
○ Myocardial Infarction	G30	Latest
○ Peripheral Vascular Disease	G73	Latest
○ Stroke / CVA	G66	Latest
○ Cerebrovascular Disease G6		Latest

NB: Read Codes on Torex may be different from those on EMIS or System One

Appendix 32

EMIS Search Strategy for Type 2 Diabetes Data Collection

Building up the search requires a methodical and stepwise approach. The EMIS search methodology and subsequent preparation of the Excel spreadsheets is described here.

The first step is to build a simple search of the practice population of interest as follows:

From the main menu select ST (Search and Statistics)
Select B (Patient searches)
Select A (Build and perform new search)
Select A (Add a feature) and proceed to build up a simple search on todays practice population. In this case All Type 2 diabetics currently on the practice register.
When no more features are required, enter 'Return' and at the prompt 'Are the features correct?' Enter 'Yes'
Name the search and store in an appropriate area of the search directory.
At the prompt 'Run the search now?' enter 'Yes'

When notified that the search is complete, go to 'Search Results'. Access the table showing distribution by age and sex (Korner bands). Details relating to practice population and percentages of patients with T2DM are provided and documented.

This search may now be used to build up a report containing data on all of the parameters required for export to excel.

Building the Export Report

Enter S (Search results) and access the basic search
Enter F (Report names and Addresses and Aspects of Patient Records)
Enter A (Add a new report)
The search can now be built up in a stepwise manner from the following screen:

Add Aspect to Collection	
A. Registration details	B. Registration status
C. Diary or recall dates	D. Clinical aspect of record
E. Present Medication	F. Past Medication
G. Patient Number	H. GP National Code
I. Consultation	P. Problem Titles
J. Age	T. Temporary Number

The patient number, age and gender (from registration details) are included. All other aspects of the search relate to present or past medication and clinical aspects of the patient record (ie E, F and D).

When each aspect of the record is accessed, the user is prompted and given the option to include associated information in the report. These include date range, whether latest value only is require, date of entry, Read Code, code description, numerical value. For parameters such as whether HbA1c, BP and lipids have been measured within a specified time period, it is necessary to define a date range. It is also necessary to ensure that data on recorded values is collected. The code

description and term used is not necessary in terms of data collection. However, it is necessary to ensure that the terms and codes used in the search extract the data required. It is possible to enter dates in the future so if running the same audit elsewhere or again, the appropriate information can be picked op over the time period of the data collection. Ideally, the 'latest only' function is specified in order to obtain single entries in line for each patient.

Once collected, the search is saved (F8) and named appropriately. The attached EMIS screen dump is an example of how the search is displayed from the pilot data collection (prior to finalisation of the parameters required). It provides a view of the EMIS screen including a summary of search strategy and detail relating to each parameter which will be reported. The search can now be exported to Excel using the 'P' function (Print, view or export report)

The report destination is Microsoft Excel (Excel must be the default spreadsheet). EMIS will create a spool file. Once complete, Search and Statistics module is exited by returning to the main menu. Once the search and report has been created and saved, it can be exported to a floppy disk and shared with other practices. However, once completed, it is not possible to alter the pre-determined dates.

The Excel spread sheet must now be tidied. A single row is inserted at the top and each column given an appropriate title referring to the data in it. Duplicate patients are deleted. (EMIS may export data relating to individual patients more than once for example when entering past medication data as in this audit). It is extremely important at this stage to check that all or the columns have data entered (if available) as some practices may use different Read Codes or different descriptors (terms) for the same parameter. If not, it is necessary to amend the report using the relevant Read Code or descriptor used by the practice and rerun the report and re-export the data into Excel. The file is then saved as an excel workbook for the practice if required. A copy is saved on a memory stick for data handling.

Appendix 33

EMIS Search Strategy for NSAIDs Data Collection

Building up the search requires a methodical and stepwise approach. The EMIS search methodology is described here.
NB: EMIS NSAID search detects all patients on low dose aspirin which need to be excluded (unless on NSAID)
The first step is to build a simple search of the practice population of interest as follows:

First EMIS Search
From the main menu select ST (Search and Statistics)
Select B (Patient searches)
Select A (Build and perform new search)
Select A (Add a feature) and proceed to build up a simple search on todays practice population.
Select E Present Medication NSAIDs

All Drugs	
Current/Past/Both	C
Acutes/Repeats/Autos/All	A
Issued Between	01.09.09 – 01.09.10 (1 Year, to date)

Continue
Name the search and store in an appropriate area of the search directory.
At the prompt 'Run the search now?' enter 'Yes'

First Report
When search complete, go to 'Search Results'
Select search
F report names and addresses plus aspect of patient record
A Add new report
E present medication: G drug group NSAIDs
P print
Export to excel. In Excel sort NSAIDs alphabetically
Highlight products containing low dose aspirin

Second EMIS Search
Return to build and perform new search on todays practice population
Select E Present Medication - NSAIDs

All Drugs	N

(Do not select All Drugs. Scroll down, use the space bar to exclude low dose aspirin products highlighted above from search)

Current/Past/Both	C
Acutes/Repeats/Autos/All	A
Issued Between	01.09.09 – 01.09.10 (1 Year, to date)

Continue
Name the search and store in an appropriate area of the search directory.
At the prompt 'Run the search now?' enter 'Yes'

Appendix 33 (Cont.)

Second Report

When search complete
Select F - Report names and addresses plus aspect of patient record
Add new report
Add the following aspects
:

G Patient ID
A Sex M/F
J Age in years
E Present medication: NSAID do not include drug group
Aspirin (G) (T)
PPI
Compound antidepressants

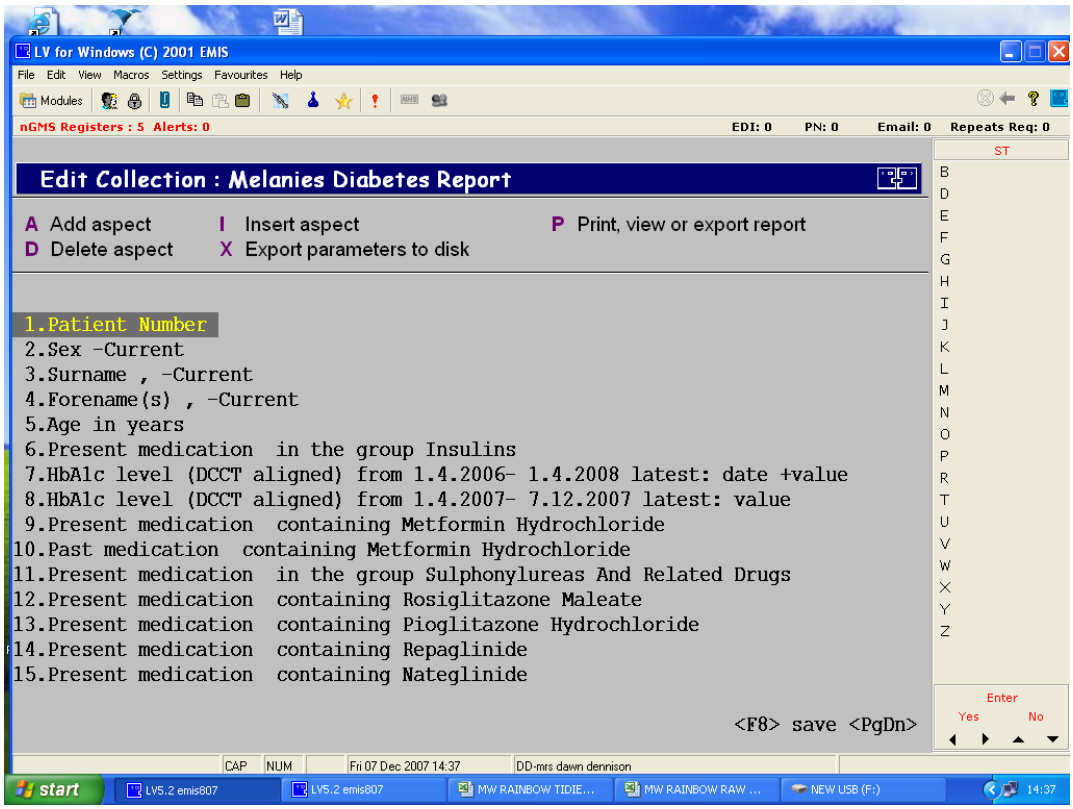
D Clinical aspect (select only latest)

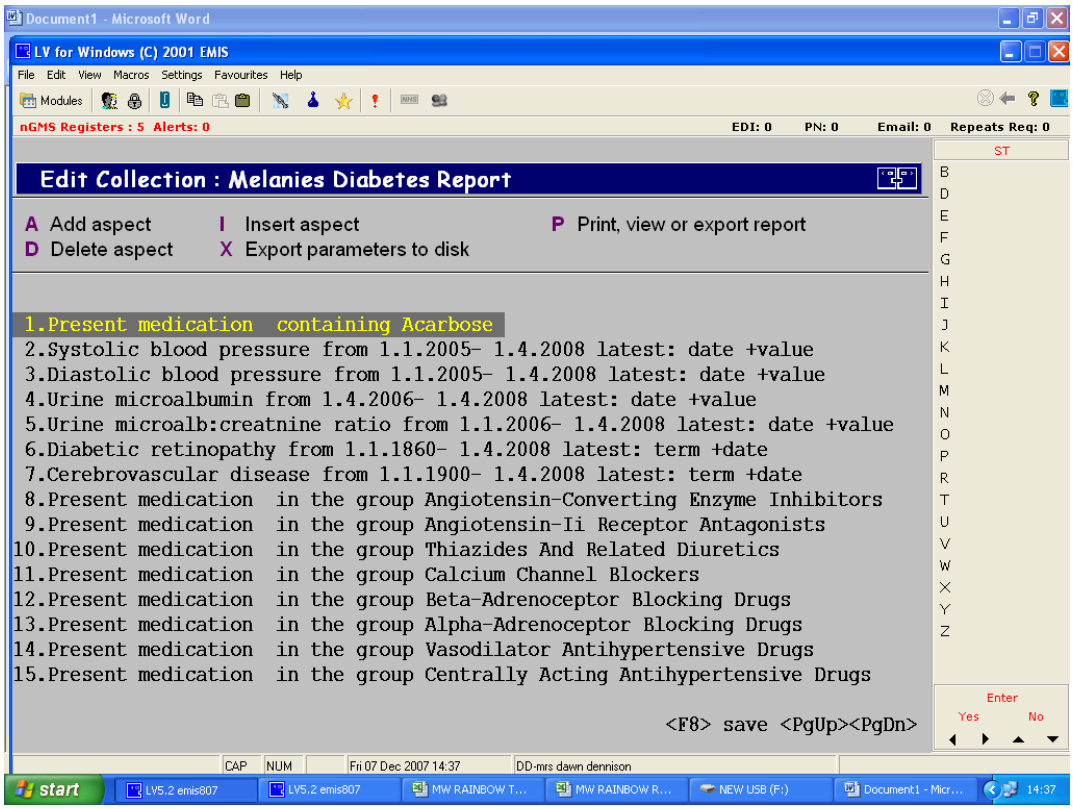
	Read Code		
Peptic Ulcer	(J130)		Latest
MI	(G30)		Latest
IHD	(G3)		Latest
Heart Failure	(G58)		Latest
CKD3	(1z12)		Latest
CKD4	(1z13)		Latest
CKD5	(1z14)		Latest
Peripheral vascular disease		(G73)	Latest
Stoke & CVA		(G66)	Latest
Cerebrovascular disease		(G6)	Latest

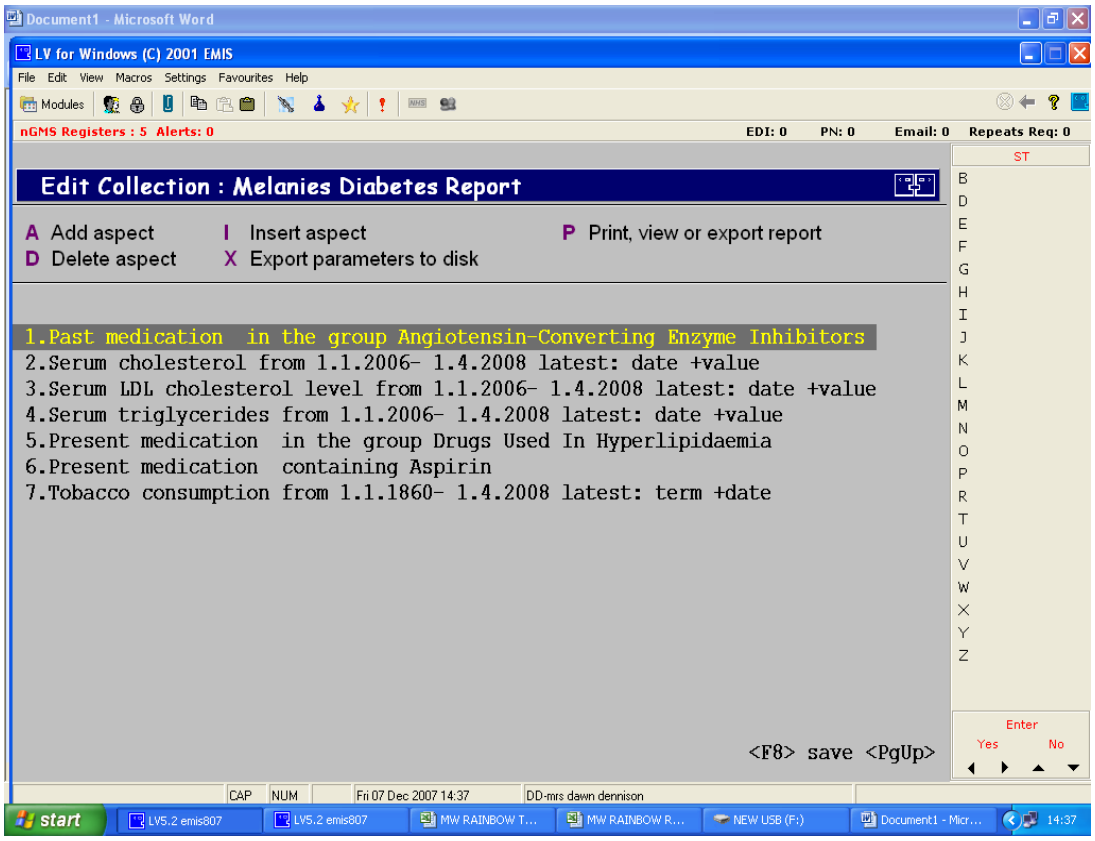
Save and export to Excel

Appendix 34

Sample Search Output – EMIS

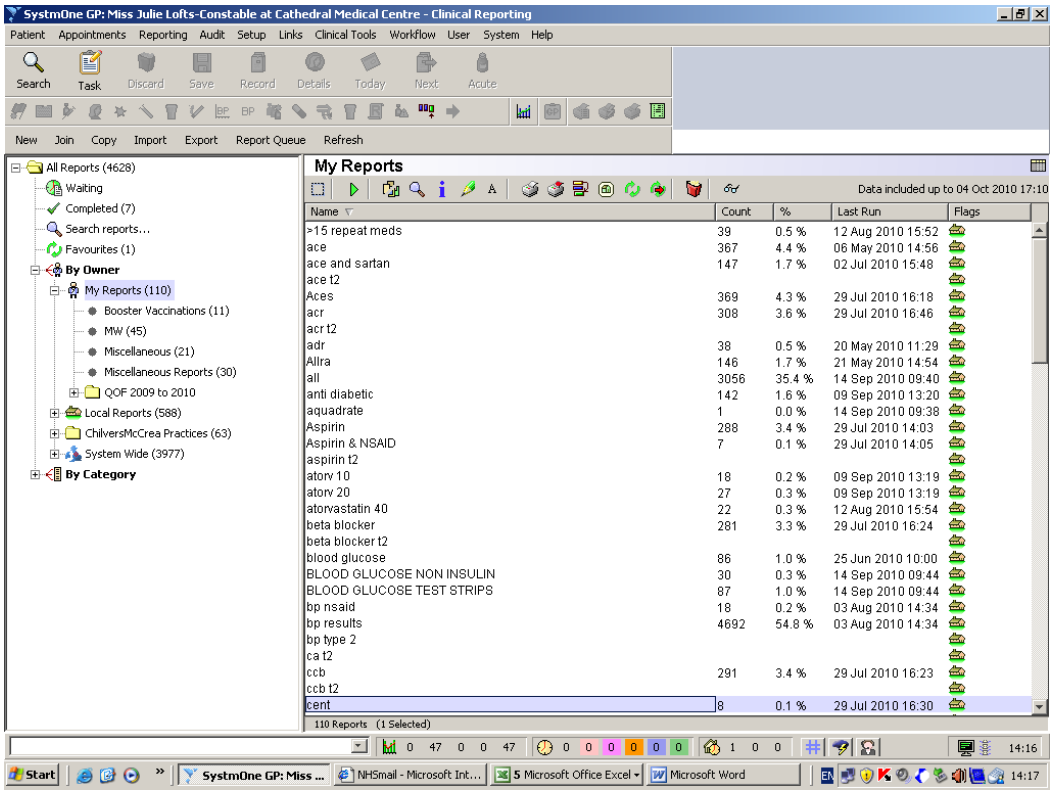


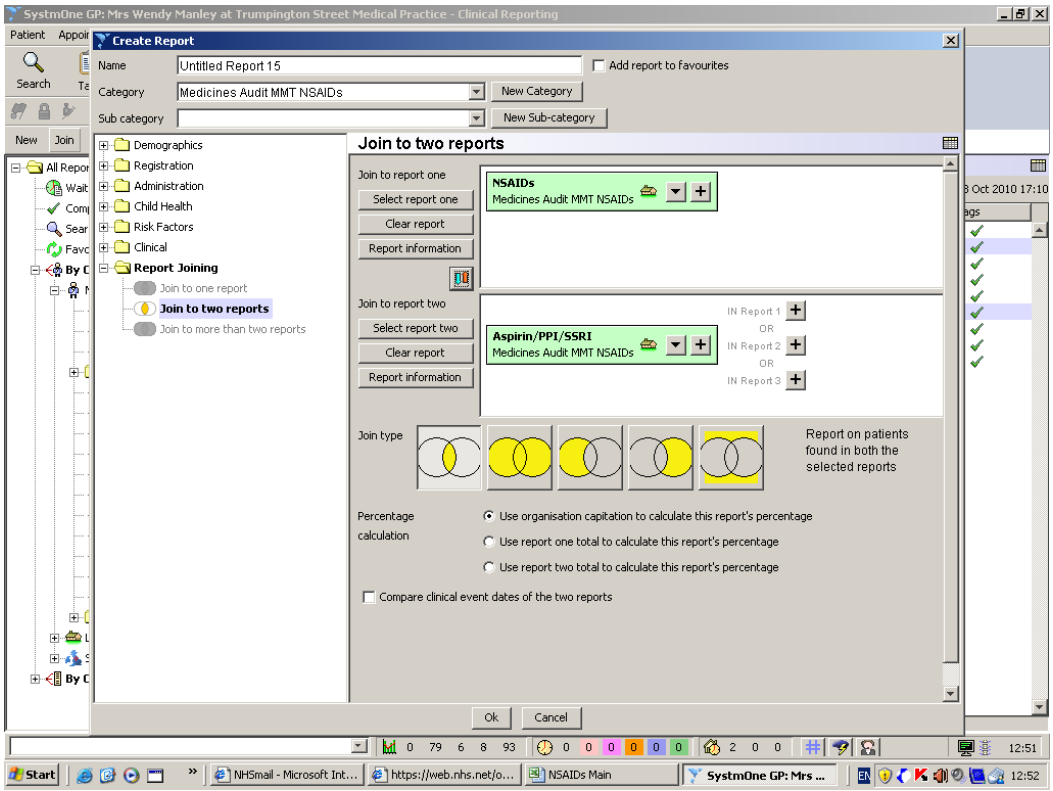



Document1 - Microsoft Word
LV for Windows (C) 2001 EMIS
File Edit View Macros Settings Favourites Help
Modules
nGMS Registers : 5 Alerts: 0
EDI: 0 PN: 0 Email: 0 Repeats Req: 0
Edit Collection : Melanies Diabetes Report
A Add aspect
D Delete aspect
I Insert aspect
X Export parameters to disk
P Print, view or export report
1.Past medication in the group Angiotensin-Converting Enzyme Inhibitors
2.Serum cholesterol from 1.1.2006- 1.4.2008 latest: date +value
3.Serum LDL cholesterol level from 1.1.2006- 1.4.2008 latest: date +value
4.Serum triglycerides from 1.1.2006- 1.4.2008 latest: date +value
5.Present medication in the group Drugs Used In Hyperlipidaemia
6.Present medication containing Aspirin
7.Tobacco consumption from 1.1.1860- 1.4.2008 latest: term +date
<F8> save <PgUp>
ST
B D E F G H I J K L M N O P R T U V W X Y Z
Enter
Yes No
CAP NUM Fri 07 Dec 2007 14:37 DD-mrs dawn dennison
start
LV5.2 emis807
LV5.2 emis807
MW RAINBOW T...
MW RAINBOW R...
NEW USB (F:)
Document1 - Micr...
14:37

Appendix 34 (Cont.)

Sample Search Outputs – System One





Appendix 34 (Cont.)

Sample Search Outputs – Torex (Rep Aid)

1,"1Rep-D1825E5D-8879-F44D-852B-631C68522CF6",1,"N",,"New Report","Last run: Tue 16 November 2010 14:00:24
Run time: 2 m : 3 s
Patients: 687

Last run: Tue 16 November 2010 14:51:57
Run time: 5 m : 36 s
Patients: 685

Last run: Fri 23 September 2011 11:10:19
Run time: 8 m : 41 s
Patients: 241","Tue 16/11/10",#FALSE#,"",#FALSE#,"","","",#TRUE#,,,,,,1,#TRUE#,,,,,,,"",,#TRUE#," Patient ID",#FALSE#,#FALSE#,,,#FALSE#
2,"2ID-378F8F5A-7DEF-514E-BAE0-081315021D26",2,1,"1Rep-D1825E5D-8879-F44D-852B-631C68522CF6","2ID","Full
GMS","0","either",120,0,0,0,"","","","",#FALSE#,#FALSE#,"False",#FALSE#,"",#FALSE#,#FALSE#,"",#FALSE#,0,0,,,,#TRUE#," first name",#FALSE#,18366,,#FALSE#,""
3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2",4,2,"2ID-378F8F5A-7DEF-514E-BAE0-081315021D26","NSAIDS L12M",#FALSE#,"j2, j2, j21, j211, j211, j212, j21y, j21z, j22,
j221, j222, j223, j224, j225, j226, j227. j228, j229, j22A, j22B, j22C, j22D, j22E, j22F, j22G, j22H, j22l, j22J, j22K, j22L, j22M, j22N. j22O, j22P, j22Q, j22R, j22S, j22T, j22U, j22V, j22W, j22X,
j22X, j22X, j22Y, j22Z, j22a, j22b, j22c, j22d, j22e, j22f, j22g, j22h, j22i, j22j, j22k, j22l, j22m, j22n, j22o, j22o, j22p, j22q, j22r, j22s, j22t, j22u, j22v, j22w, j22x, j22y, j22z, j22z, j23, j231, j232,
j233, j234, j24, j241, j242, j243, j244, j245, j246, j247, j248, j249, j24A, j24B, j24C, j24D, j25, j251, j252, j253, j254, j255, j256, j257, j258, j259, j25A, j25B, j25y, j25z, j26, j261, j262, j263,
j264, j27. j271, j272, j273, j274, j275, j27x, j27y, j27z, j28, j281, j282, j283, j284, j285, j286, j287, j288, j289, j28A, j28B, j28C, j28D, j28E, j28F, j28G, j28H, j28l, j28J, j28K, j28M, j28N, j28O,
j28O, j28P, j28R, j28S, j28T, j28U, j28V, j28V, j28W, j28X, j28Y, j28Y, j28Y, j28Z, j28a, j28b, j28c, j28d, j28e, j28f, j28g, j28h, j28i, j28j, j28k, j28l, j28m, j28n, j28o, j28p, j28q, j28r, j28s, j28t,
j28u, j28v, j28w, j28w, j28w, j28x, j28y, j28z, j28z, j29, j29, j291, j291, j292, j292, j293, j293, j293, j294, j295, j296, j297, j298, j299, j29A, j29A, j29A, j29B, j29B, j29B, j29C, j29C, j29C, j29D,
j29D, j29D, j29E, j29E, j29E, j29F, j29G, j29H, j29J, j29K, j29a, j29b, j29c, j29d, j29e, j29f, j29g, j29h, j29i, j29j, j29k, j29l, j29m, j29n, j29o, j29p, j29p, j29p, j29q, j29r, j29s, j29t, j29u, j29v,
j29v, j29w, j29y, j29y, j29z, j29z, j29z, j2a, j2a1, j2a2, j2a3, j2a4, j2a5, j2a6, j2a7, j2a8, j2a9, j2aA, j2aB, j2aC, j2aD, j2aE, j2aF, j2aG, j2aH, j2aI, j2aJ, j2aK, j2aL, j2aM, j2aO, j2aP, j2aQ,
j2aQ, j2aR, j2aR, j2aa, j2ab, j2aw, j2ax, j2ay, j2az, j2b, j2b1, j2b2, j2b3, j2b4, j2b5, j2b6, j2b7, j2b8, j2b9, j2bA, j2bB, j2bC, j2bD, j2bx, j2by, j2bz, j2c, j2c1, j2c2, j2c3, j2c4, j2c5, j2c6, j2c7,
j2c8, j2c9, j2cA, j2cB, j2cC, j2cD, j2cE, j2cF, j2cG, j2cH, j2cI, j2cJ, j2cK, j2cL, j2cM, j2cN, j2cO, j2ca, j2cb, j2cc, j2cd, j2ce, j2cf, j2cg, j2ch, j2ci, j2cj, j2ck, j2cl, j2cm, j2cn, j2co, j2cp, j2cq,
j2cr, j2cs, j2ct, j2cu, j2cv, j2cw, j2cx, j2cx, j2cy, j2cz, j2d, j2d1, j2d2, j2d3, j2d4, j2d5, j2d6, j2d7, j2d8, j2e, j2e1, j2e2, j2e3, j2e4, j2e5, j2e6, j2e7, j2e8, j2e9, j2eA, j2eB, j2ea, j2eb, j2ec, j2ed,
j2ee, j2ef, j2ev, j2ew, j2ex, j2ey, j2ez, j2f, j2f1, j2f2, j2fy, j2fz, j2g, j2g1, j2g2, j2g3, j2g4, j2g5, j2gx, j2gy, j2gz, j2h, j2h1, j2h2, j2h3, j2hy, j2hz, j2i, j2i, j2i1, j2i1, j2i1, j2i1, j2i2, j2i2, j2j, j2j1,
j2j2, j2k, j2k, j2k1, j2k2, j2k3, j2k4, j2k5, j2k6, j2l, j2l1, j2l2, j2l3, j2l4, j2l5, j2l6, j2l7, j2l8, j2m, j2m1, j2m2, j2n, j2n1, j2n2, j2n3, j2n4, j2n5, j2n6, j2n7, j2n8, j2o, j2o1, j2o2, j2o3, j2o4, j2o5,
j2o6, j2o6, j2o7, j2o8, j2o9, j2oA, j2oB, j2oC, j2oD, j2oE, j2oF, j2oG, j2oH, j2oJ, j2oK, j2oK, j2oL, j2oM, j2oN, j2oO, j2ol, j2om, j2oo, j2op, j2oq, j2or, j2os, j2ot, j2ou, j2ov, j2ow, j2ox, j2oy,
j2oz, j2p, j2p1, j2p2, j2p3, j2p3, j2p3, j2p4, j2p5, j2p6, j2p6, j2p7, j2p8, j2p9, j2pA, j2pB, j2pC, j2pD, j2pE, j2pF, j2pG, j2pH, j2pI, j2pJ, j2pK, j2pL, j2pM, j2pN, j2pO, j2pP, j2pQ, j2pR, j2pS,
j2pT, j2pU, j2pV, j2pW, j2pX, j2pY, j2pZ, j2pa, j2q, j2q1, j2qz, j2r, j2r1, j2r2, j2r3, j2rx, j2ry, j2rz, j2s, j2s1, j2s2, j2s3, j2sx, j2sy, j2sz, j2t, j2t1, j2t2, j2ty, j2tz, jA2, jA2y, jA2z, jA5, jA51, jA52,
jA53, jA58","","NON-STEROIDAL ANTI-INFLAMM NOS and others","",0,"","Thu 30/9/2010","Sat
1/10/2011","True",#TRUE#,#FALSE#,"","True","False","False","False",#TRUE#,#TRUE#,"Authorisation","True",,2,#TRUE#," surname",#FALSE#,241,"",#FALSE#,#FALSE#
4,"4Drug-16931555-8894-4E4C-813E-6D9AD6C7E6F3",4,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","Aspirin",#FALSE#,"bu23, bu24, bu25, bu2A, bu2B, bu2D, bu2E, bu2F,
bu2G, bu2H, bu2K, bu2c","","ASPIRIN 75mg disp tabs and
others","",0,"","","","True","True","False","","True","False","False",#TRUE#,#TRUE#,"Authorisation","True",,3,#TRUE#," sex",#FALSE#,25,"",#FALSE#,#FALSE#
5,"5Drug-04D32D0E-FF61-FE44-82D5-A42B0D5950FB",4,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","PPI",#FALSE#,"a6b, a6b1, a6b1, a6b2, a6b3, a6b4, a6b5, a6b5,
a6b6, a6b7, a6b7, a6b8, a6b9, a6bA, a6bB, a6bC, a6bD, a6bE, a6bF, a6bG, a6bH, a6bI, a6bJ, a6bK, a6bL, a6bM, a6bN, a6bO, a6bP, a6bu, a6bv, a6bw, a6bx, a6by, a6bz, a6c, a6c1,
a6c2, a6c3, a6c4, a6c5, a6c6, a6c7, a6c8, a6c9, a6cA, a6e, a6e1, a6e2, a6e3, a6e4, a6e5, a6e6, a6f, a6f1, a6f2, a6f3, a6f4, a6h, a6h1, a6h2, a6h3, a6hx, a6hy, a6hz","","OMEPRAZOLE
and others","",0,"","","","True","True","False","","True","False","False","False",#TRUE#,#TRUE#,"Authorisation","True",,3,#TRUE#," age",#FALSE#,74,"",#FALSE#,#FALSE#
6,"6Drug-4C21C26E-D15E-2843-8FE1-4B2302665BC1",4,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","SSRI",#FALSE#,"da4, da41, da42, da43, da44, da45, da46, da47,
da48, da49, da4A, da4B, da5, da51, da52, da53, da54, da6, da61, da62, da63, da64, da65, da66, da67, da68, da7, da71, da72, da73, da74, da75, da76, da77, da78, da79, da7A, da7B,
da7C, da7D, da7E, da7F, da7G, da7H, da7I, da7J, da7K, da7L, da7M, da7N, da7O, da7P, da7Q, da7R, da7S, da7T, da7U, da7V, da7W, da7X, da7Y, da7Z, da7a, da7b, da7c, da9, da91,
da92, da93, da94, da95, da96, da97, da98, da99, da9A, da9z, daC, daC1, daC2, daC3, daC4, daC5, daC6, daC7, daC8, daC9, daCA","","FLUOXETINE HYDROCHLORIDE and
others","",0,"","","","True","True","False","","True","False","False","False",#TRUE#,#TRUE#,"Authorisation","True",,3,#TRUE#," road",#FALSE#,37,"",#FALSE#,#FALSE#
7,"7Morb-4CFA0F48-74D6-FA41-9A5F-E263D82A3E22",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","PU",#FALSE#,"J13, J130, J1300, J1301, J1302, J1303, J1304, J130y,
J130z, J131, J1310, J1311, J1312, J1313, J1314, J131y, J131z, J13y, J13y0, J13y1, J13y2, J13y3, J13y4, J13yy, J13yz, J13z","","Peptic ulcer - (PU) site unsp. and
others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#TRUE#," GP",#FALSE#,0,,#FALSE#,#FALSE#
8,"8Morb-F8FE425C-DDD4-2D4F-88A9-CDAF4E8E2C24",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","CKD",#FALSE#,"1Z10, 1Z11, 1Z12, 1Z13, 1Z14","","Chronic kidney
disease stage 1 and others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#TRUE#," post
code",#FALSE#,15,,#FALSE#,#FALSE#
9,"9Morb-61E3A627-9D85-C84E-AE53-0EA5F4ADA0C9",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","HF",#FALSE#,"G58, G58, G580, G580, G580, G580, G580, G5800,
G5801, G5802, G5803, G5804, G581, G581, G581, G581, G5810, G582, G58z, G58z, G58z, G58z","","Cardiac failure and
others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#FALSE#," surgery",#FALSE#,2,,#FALSE#,#FALSE#
10,"10Morb-CFBC0374-D4E2-9A45-B109-10AE6CBF6D28",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","Hypertension",#FALSE#,"G20, G20, G200, G201, G202, G203,
G20z, G20z","","Essential hypertension and others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#FALSE#,"
title",#FALSE#,23,,#FALSE#,#FALSE#
11,"11Morb-9083A301-1F59-6441-860E-9129FB0F9555",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","MI",#FALSE#,"G30, G30, G30, G30, G30, G30, G30, G30, G300,
G301, G3010, G3011, G301z, G302, G303, G304, G305, G306, G307, G3070, G3071, G308, G309, G30A, G30B, G30X, G30X0, G30y, G30y0, G30y1, G30y2, G30yz, G30z","","Acute
myocardial infarction and others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#FALSE#,"
house",#FALSE#,6,,#FALSE#,#FALSE#
12,"12Morb-C82524FB-D6BF-8E44-980D-AD47434290C2",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","IHD",#FALSE#,"G3, G3, G3, G3","","Arteriosclerotic heart disease
and others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#FALSE#," date of birth",#FALSE#,8,,#FALSE#,#FALSE#
13,"13Morb-9810548F-353E-D847-8668-6C8AA6027EA0",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","PVD",#FALSE#,"G73, G73, G73, G73, G730, G7300, G7301,
G7301, G730z, G731, G7310, G7311, G731z, G732, G7320, G7321, G7322, G7323, G7324, G733, G73y, G73y0, G73y1, G73y2, G73y4, G73y4, G73y5, G73y5, G73y6, G73y7, G73y8,
G73y8, G73y8, G73yz, G73z, G73z0, G73z0, G73z0, G73z1, G73zz","","Ischaemia of legs and
others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#FALSE#," phone",#FALSE#,4,,#FALSE#,#FALSE#
14,"14Morb-9D652D90-0173-6649-8FC3-2BCD272FAB95",3,3,"3Drug-74EA9EF2-632B-FA46-93AC-6DFC04B8EFF2","Stroke_CVA",#FALSE#,"G6, G60, G600, G601, G602, G603, G604,
G605, G606, G60X, G60z, G61, G61, G61, G610, G611, G612, G613, G614, G615, G616, G617, G618, G61X, G61X0, G61X1, G61z, G62, G620, G621, G622, G623, G62z, G63, G63,
G63, G630, G631, G631, G631, G632, G633, G634, G63y, G63y0, G63y1, G63z, G64, G64, G64, G64, G640, G6400, G641, G641, G6410, G64z, G64z, G64z, G64z0, G64z1, G64z1,
G64z2, G64z3, G64z4, G65, G65, G65, G65, G65, G650, G650, G651, G6510, G652, G653, G654, G655, G656, G65y, G65z, G65z0, G65z1, G65zz, G66, G66, G66, G66, G66, G660, G661,
G662, G663, G664, G665, G666, G667, G668, G669, G67, G670, G670, G671, G6710, G6711, G671z, G672, G672, G673, G6730, G6731, G6732, G6733, G674, G6740, G675, G676,
G6760, G677, G6770, G6771, G6772, G6773, G6774, G678, G679, G67y, G67z, G68, G680, G681, G682, G683, G68W, G68X, G6W, G6X, G6y, G6z","","Cerebrovascular disease
and others","",0,"","","False","False","False",#TRUE#,"True","False","False",#FALSE#,"",#FALSE#,#FALSE#,"False","",,3,#FALSE#," health authority",#FALSE#,4,,#FALSE#,#FALSE#
,,,,,,,

Appendix 35

Data Record Form

T2DM
Practice

	Baseline		**Post Intervention**		**Shift**
	No.	**%**	**No.**	**%**	**%**
Practice Population					
Patients on T2DM Register					
Medication Patients on:					
Metformin					
ACE-I / A-II-A					
Statin / LLA					
Aspirin/Antiplatelet					
Clinical Outcomes					
Blood Glucose HbA1c ≤ 7.5%(58mmol/ml) HbA1c ≤ 9.0%(75mmol/ml) HbA1c ≥ 9.0%/not recorded					
Blood Pressure BP ≤ 140/80mmHg					
Renal - ACR					
ACR Measured					
Patients with Microalbuminuria (of those measured)					
Those with m/a on ACE-I / A-II-A					
Those with m/a with BP ≤ 135/80mmHg					
Blood Lipids TC ≤ 4mmol/l TC ≤ 5mmol/l LDL ≤ 2mmol/l TGs ≤ 2.3mmol/l					

Appendix 35 (Cont.)

Data Record Form

NSAIDs
Practice

	Baseline		**Post Intervention**		**Shift**
	No.	**%**	**No.**	**%**	**%**
Practice Population					
Patients on NSAID					
Diclofenac					
Ibuprofen					
Diclofenac					
Coxibs					
Others					
Total					
Ib + Na					
Patients ≥ 65					
Medication					
Aspirin					
PPI					
Aspirin + PPI					
SSRI					
Aspirin + SSRI					
Risk Factors					
PU					
CKD					
3					
4					
5					
Total					
Cardiovascular					
IHD					
PVD					
Cerebrovascular					
Total					
Hypertension					

Appendix 36

An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Aide-Memoire

Proposed Topic Guide – Pre-Intervention

Intended to evaluate GP perspective in relation to perceptions, attitudes, knowledge and clinical behaviour before delivering the intervention.

Tell me a little about yourself. Experience, interests

- Have you had specific training in EBM? In curriculum at college? Since college?

- Has it equipped you to practice in an evidence based way?
- What about critical appraisal?

- *General perceptions of EBM*

    - Definition of EBM Defining EBM
    - Opinion of EBM

- *EBM and Clinical Practice*

    - How does EBM affect your clinical practice?
    - Are you able to incorporate EBM in your prescribing practice?
    - Are there any particular triggers which might prompt you to seek evidence based information to inform you practice, including prescribing decisions?
    - Where would you normally access information from to inform prescribing decisions?
    - What do you consider as evidence-based sources of information? Would you actively seek them (if at all) to inform prescribing decisions?
    - Guidelines, would you question them?
    - Pressures to prescribe

- Do you perceive any barriers to incorporation of EBM into prescribing decisions
    - How overcome them?

- View of prescribing advisers Role, knowledge, experience
    - Current, previous experience

- What if any expectations do you have in relation to the proposed intervention.

- What is your motivation for taking part in study
    - Expectations

Appendix 37

An Evaluation of Evidence-Based Prescribing Support from Primary Care Prescribing Advisers on GP Prescribing Behaviour.

Aide-Memoire

Proposed Topic Guide – Post-Intervention

Intended to evaluate GP perspective in relation to perceptions, attitudes, knowledge and clinical behaviour following delivery of the intervention.

- Tell me a bit about yourself.
    - How long a GP? Experience Special Interests

General perceptions of EBM

- Do you have a view / perception on practice of evidence based medicine
    - What it is? How would you define it? Training?

EBM and Clinical Practice

- Do you have a view on EBM?
    - How does EBM affect your clinical practice
    - Do you consider yourself to be an evidence based practitioner?
    - Do you incorporate EBM into your clinical decision making?

- Before the prescribing adviser visits, where / how would you normally access information from to inform prescribing decisions?
    - Has your approach to accessing prescribing information changed since the intervention?

- What was your personal experience of 'prescribing advice' before the intervention
    - ? Support from MMT
    - ? Support from individual pharmacists (or technicians)
    - ? Support from prescribing adviser

Attitudes toward the evidence-based intervention

- Did you have any idea / preconceptions of what the 'intervention' was going to involve?

- Can you tell me about the visits?
    - What happened? Content.
    - What was your experience / view of the practice visits
    - Different from previously?
    - Is there anything that worked particularly well / not so well
    - What, if any, are the benefits of this approach?

- What did you think of 'the intervention' itself in the practice?
    - As a means of communicating (evidence based) prescribing information (with MMT, with each other).
    - Facilitating discussion
    - Research into practice Was the evidence base promoted?
    - Agreed Actions

- What was your view of the support delivered by the prescribing adviser as source of information (evidence based or otherwise)
    - Is that different from your previous experience?
    - Any specific observations

- View of prescribing advisers
    - Role, knowledge, experience
    - What makes a good pharmacist in fulfilling this role?

- Since implementation of the intervention have your pre-intervention perceptions changed
    - Prescribing advisers / MMT?
    - Attitude to EBM?

- What is your view of the suitability and usefulness of written information provided
    - Evidence
    - Data (feedback)

- Did anything change over the intervention period ie from baseline to Visit 4?
    - Eg development of relationship between pharmacist and the partners?
    - Trust?
    - Does this role have to be carried out by a pharmacist?

Impact of the evidence-based intervention

- What impact if any do you think the intervention has had
    - On you personally
    - On your prescribing practice?

- What impact if any do you think the intervention has had
    - On the Practice as a whole
    - On practice partners as colleagues and clinicians (and PNs if attended).
    - On prescribing practice.

- Has the intervention added value to you and / or your practice
    - Have you become better prescribers
    - Has it reduced any perceived barriers to prescribing

- Do you consider that your knowledge and education about drugs and therapeutics increased as a result of the intervention? In relation to:
    - Type 2 diabetes
    - Appropriate use of NSAIDs
- Has it made you more aware of the evidence behind prescribing recommendations (and its robustness)

- What if this approach were rolled out more widely?
    - Would this be a good idea
    - What advice / recommendations would you give

- Is there anything else you want to add?

Appendix 38

Prescribing Data
Summary Statistics for Non-Steroidal Anti-Inflammatory Drugs

Total NSAIDs

Descriptives				
			Statistic	**Std. Error**
NSAIDDiff	**Mean**		-10.823	4.088
	95% Confidence Interval for Mean	Lower Bound	-19.28	
		Upper Bound	-2.366	
	5% Trimmed Mean		-8.263	
	Median		-4.62	
	Variance		401.085	
	Std. Deviation		20.0271	
	Minimum		-83.3	
	Maximum		8.3	
	Range		91.5	
	Interquartile Range		21.6	
	Skewness		-2.238	0.472
	Kurtosis		6.749	0.918

Table 38.1 Summary Statistics for Total NSAIDs

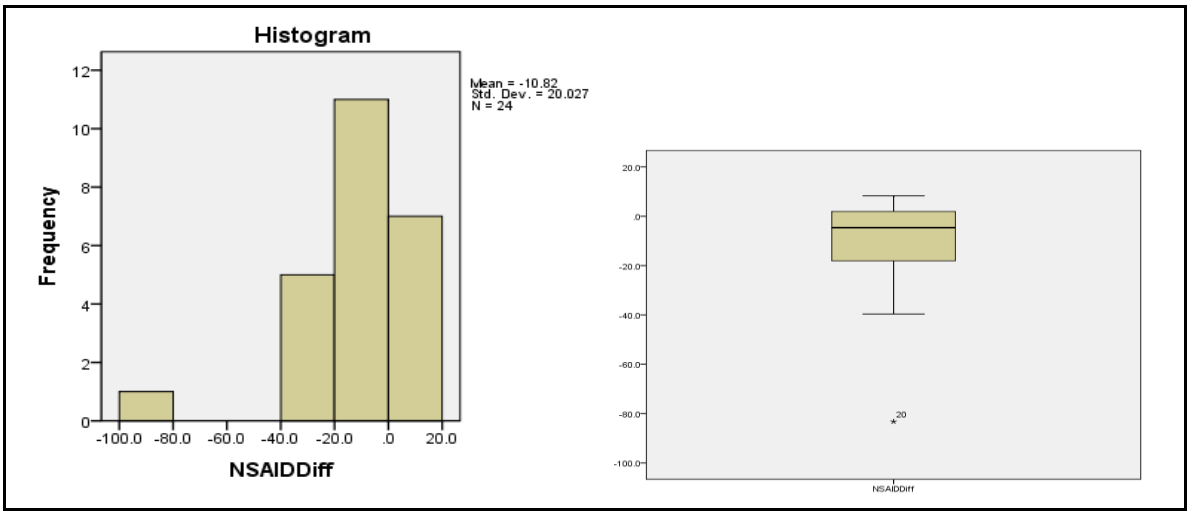


Table 38.2 Total NSAIDs Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
NSAIDDiff	0.171	24	0.067	0.79	24	0

a Lilliefors Significance Correction

Table 38.3 Total NSAIDs Tests of Normality

Appendix 38 (Cont.)

Prescribing Data
Summary Statistics for Non-Steroidal Anti-Inflammatory Drugs

Diclofenac

Descriptives				
			Statistic	**Std. Error**
DicDiff	**Mean**		-14.079	3.6178
	95% Confidence Interval for Mean	Lower Bound	-21.563	
		Upper Bound	-6.595	
	5% Trimmed Mean		-12.007	
	Median		-11.705	
	Variance		314.118	
	Std. Deviation		17.7234	
	Minimum		-76.6	
	Maximum		5.2	
	Range		81.8	
	Interquartile Range		22.5	
	Skewness		-2.008	0.472
	Kurtosis		5.872	0.918

Table 38.4 Summary Statistics for Diclofenac

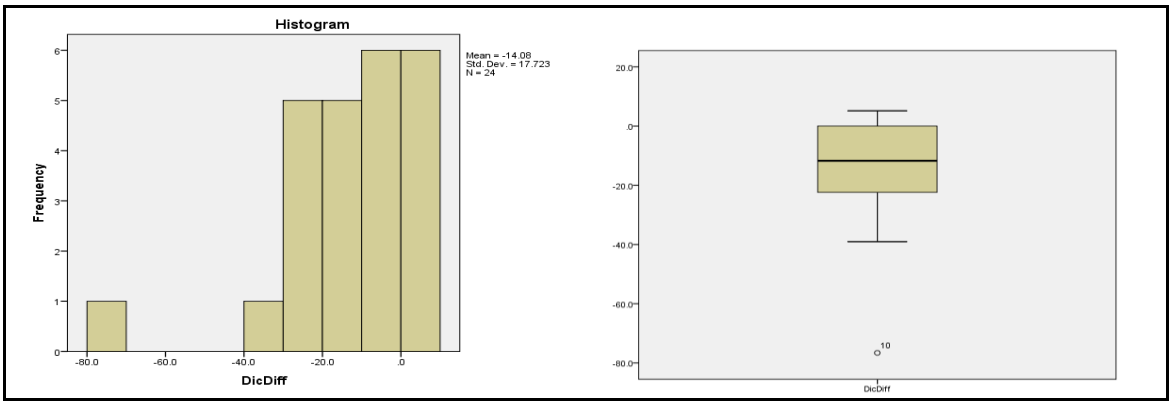


Table 38.5 Diclofenac Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
DicDiff	0.147	24	0.194	0.821	24	0.001

a Lilliefors Significance Correction

Table 38.6 Diclofenac Tests of Normality

Appendix 38 (Cont.)

Prescribing Data
Summary Statistics for Non-Steroidal Anti-Inflammatory Drugs

COX-2 Inhibitors

Descriptives				
			Statistic	**Std. Error**
COXDiff	**Mean**		-0.693	0.5353
	95% Confidence Interval for Mean	Lower Bound	-1.801	
		Upper Bound	0.414	
	5% Trimmed Mean		-0.578	
	Median		0.115	
	Variance		6.877	
	Std. Deviation		2.6223	
	Minimum		-6.4	
	Maximum		2.9	
	Range		9.4	
	Interquartile Range		4.5	
	Skewness		-0.853	0.472
	Kurtosis		-0.377	0.918

Table 38.7 Summary Statistics for COX-2 Inhibitors

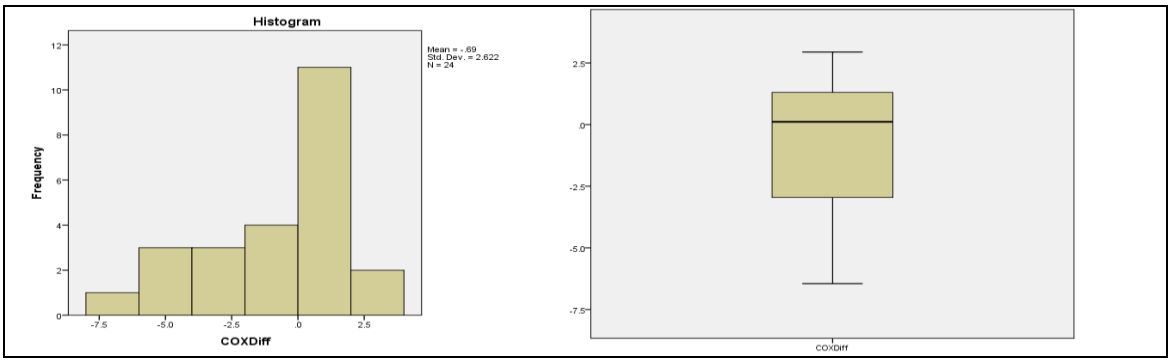


Table 38.8 COX-2 Inhibitors Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
COXDiff	0.216	24	0.005	0.894	24	0.016

a Lilliefors Significance Correction

Table 38.9 COX-2 Inhibitors Tests of Normality

Appendix 38 (Cont.)

Prescribing Data
Summary Statistics for Non-Steroidal Anti-Inflammatory Drugs

Ibuprofen

Descriptives				
			Statistic	**Std. Error**
IbuDiff	**Mean**		-0.679	1.1323
	95% Confidence Interval for Mean	Lower Bound	-3.022	
		Upper Bound	1.663	
	5% Trimmed Mean		-0.795	
	Median		-0.67	
	Variance		30.771	
	Std. Deviation		5.5472	
	Minimum		-10.2	
	Maximum		11	
	Range		21.2	
	Interquartile Range		6.3	
	Skewness		0.393	0.472
	Kurtosis		0.004	0.918

Table 38.10 Summary Statistics for Ibuprofen

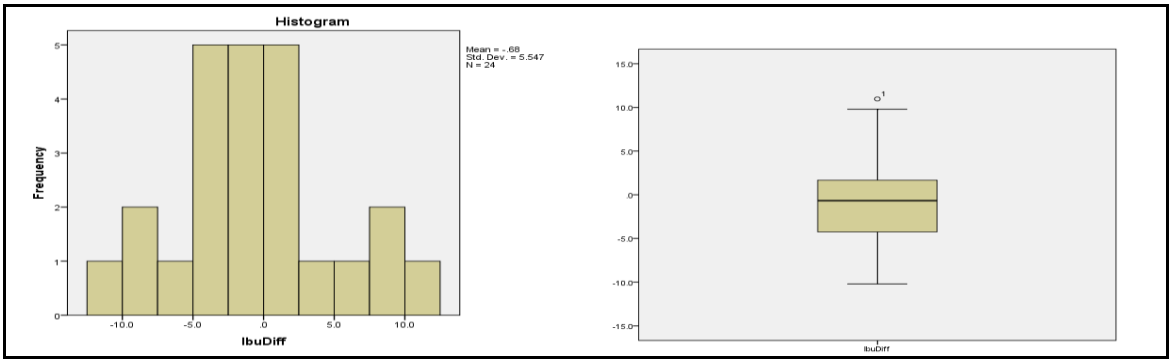


Table 38.11 Ibuprofen Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
IbuDiff	0.127	24	.200*	0.963	24	0.503

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

Table 38.12 Ibuprofen Tests of Normality

Appendix 38 (Cont.)

Prescribing Data
Summary Statistics for Non-Steroidal Anti-Inflammatory Drugs

Naproxen

Descriptives				
			Statistic	**Std. Error**
NapDiff	**Mean**		7.53	3.7669
	95% Confidence Interval for Mean	Lower Bound	-0.262	
		Upper Bound	15.322	
	5% Trimmed Mean		7.331	
	Median		5.07	
	Variance		340.555	
	Std. Deviation		18.4541	
	Minimum		-42	
	Maximum		62.3	
	Range		104.3	
	Interquartile Range		13.8	
	Skewness		0.287	0.472
	Kurtosis		4.314	0.918

Table 38.13 Summary Statistics for Naproxen

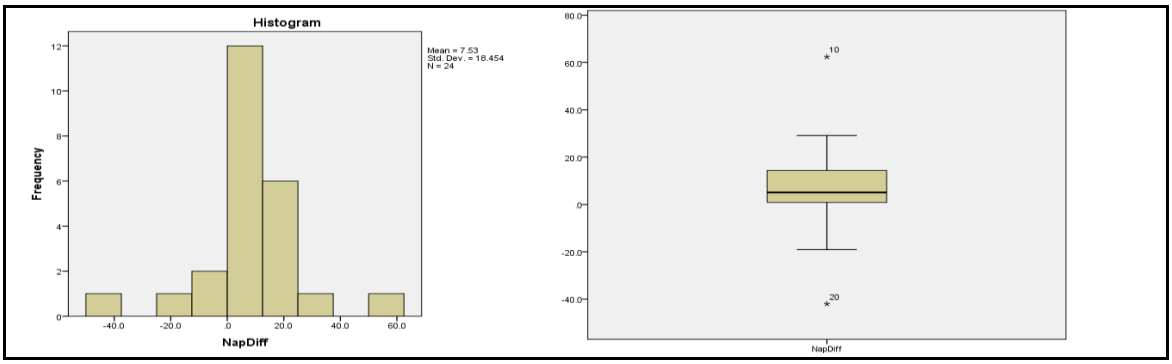


Table 38.14 Naproxen Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
NapDiff	0.214	24	0.006	0.884	24	0.01

a Lilliefors Significance Correction

Table 38.15 Naproxen Tests of Normality

Appendix 38 (Cont.)

Prescribing Data
Summary Statistics for Non-Steroidal Anti-Inflammatory Drugs

Ibuprofen and Naproxen

Descriptives				
			Statistic	**Std. Error**
IbNapDiff	**Mean**		6.797	3.7302
	95% Confidence Interval for Mean	Lower Bound	-0.919	
		Upper Bound	14.513	
	5% Trimmed Mean		7.095	
	Median		8.425	
	Variance		333.937	
	Std. Deviation		18.2739	
	Minimum		-50.8	
	Maximum		57.6	
	Range		108.4	
	Interquartile Range		16.9	
	Skewness		-0.461	0.472
	Kurtosis		5.644	0.918

Table 38.16 Summary Statistics for Ibuprofen and Naproxen

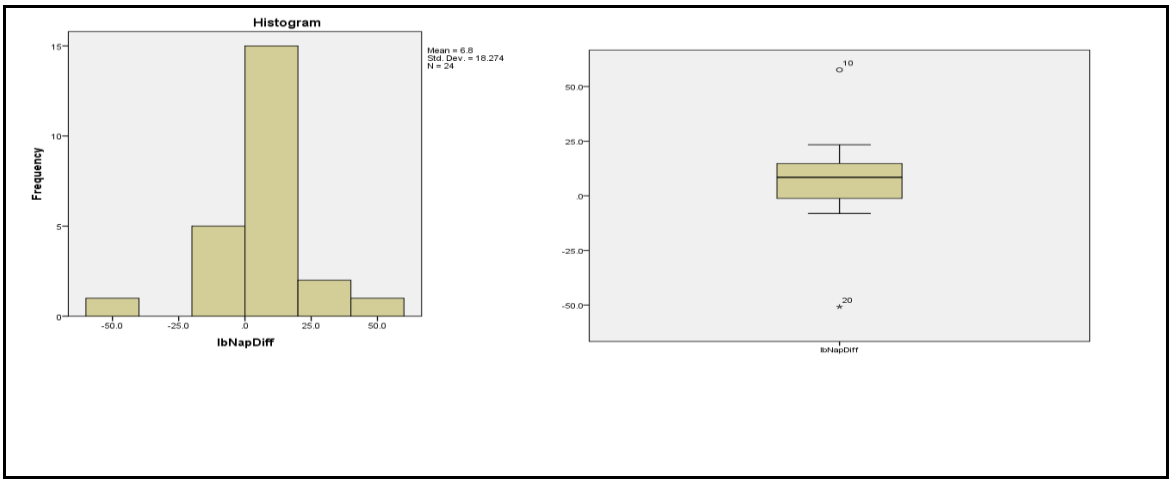


Table 38.17 Ibuprofen and Naproxen Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
IbNapDiff	0.165	24	0.088	0.854	24	0.003

Table 38.18 Ibuprofen and Naproxen Tests of Normality

Appendix 39

Prescribing Data
Summary Statistics for Drugs used in Type 2 Diabetes

Total Drugs T2DM

Descriptives				
			Statistic	**Std. Error**
AllDiff	Mean		-1.303	7.3108
	95% Confidence Interval for Mean	Lower Bound	-16.427	
		Upper Bound	13.82	
	5% Trimmed Mean		4.662	
	Median		9.24	
	Variance		1282.736	
	Std. Deviation		35.8153	
	Minimum		-157.6	
	Maximum		26.8	
	Range		184.3	
	Interquartile Range		19.5	
	Skewness		-3.893	0.472
	Kurtosis		17.105	0.918

Table 39.1 Summary Statistics for Total Drugs in T2DM

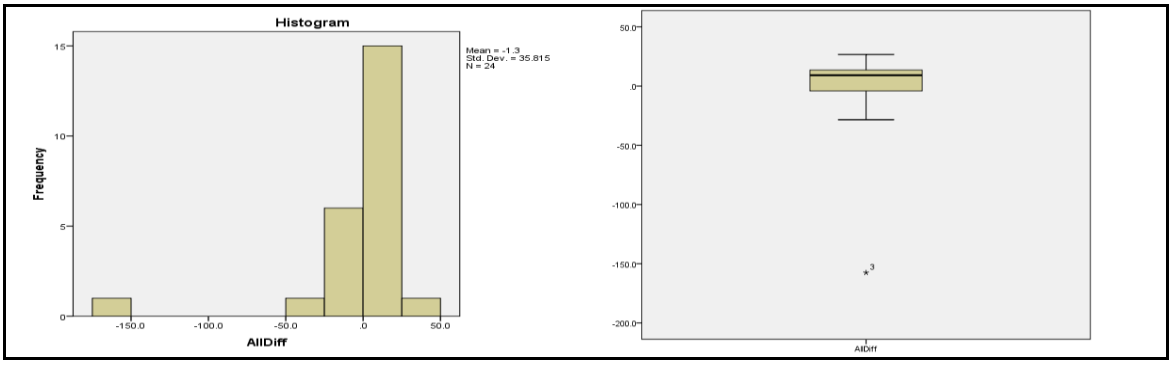


Table 39.2 Total Drugs in T2DM Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
AllDiff	0.259	24	0	0.543	24	0

a Lilliefors Significance Correction

Table 39.3 Total Drugs in T2DM Tests of Normality

Appendix 39 (Cont.)

Prescribing Data
Summary Statistics for Drugs used in Type 2 Diabetes

Metformin

Descriptives				
			Statistic	**Std. Error**
MetDiff	**Mean**		8.977	4.4386
	95% Confidence Interval for Mean	Lower Bound	-0.205	
		Upper Bound	18.159	
	5% Trimmed Mean		12.611	
	Median		14.085	
	Variance		472.836	
	Std. Deviation		21.7448	
	Minimum		-87.8	
	Maximum		27.5	
	Range		115.3	
	Interquartile Range		9.8	
	Skewness		-4.128	0.472
	Kurtosis		18.772	0.918

Table 39.4 Summary Statistics for Metformin

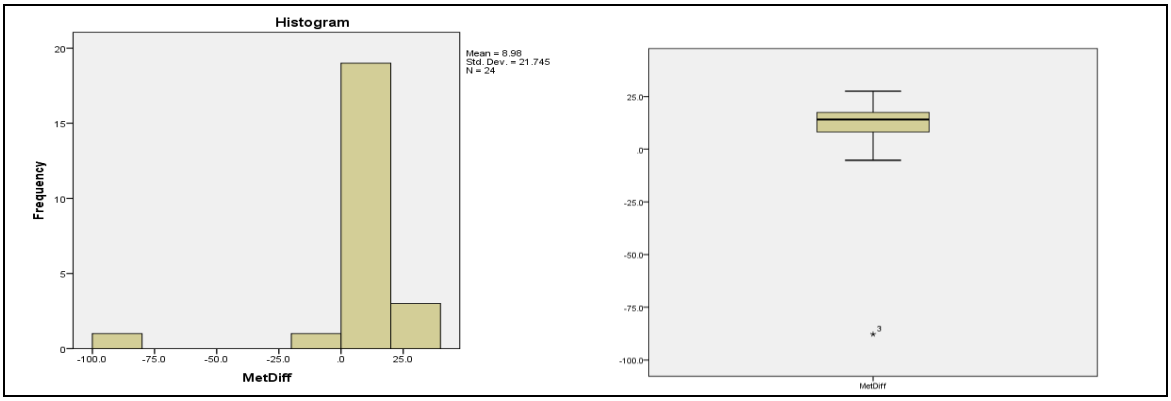


Table 39.5 Metformin Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
MetDiff	0.327	24	0	0.5	24	0

a Lilliefors Significance Correction

Table 39.6 Total Drugs in T2DM Tests of Normality

Appendix 39 (Cont.)

Prescribing Data
Summary Statistics for Drugs used in Type 2 Diabetes

Total Glitazones

Descriptives				
			Statistic	Std. Error
GlitDiff	**Mean**		-8.28	1.4505
	95% Confidence Interval for Mean	Lower Bound	-11.28	
		Upper Bound	-5.279	
	5% Trimmed Mean		-8.47	
	Median		-8.045	
	Variance		50.493	
	Std. Deviation		7.1058	
	Minimum		-19.5	
	Maximum		6.7	
	Range		26.2	
	Interquartile Range		8.4	
	Skewness		0.257	0.472
	Kurtosis		-0.274	0.918

Table 39.7 Summary Statistics for Total Glitazones

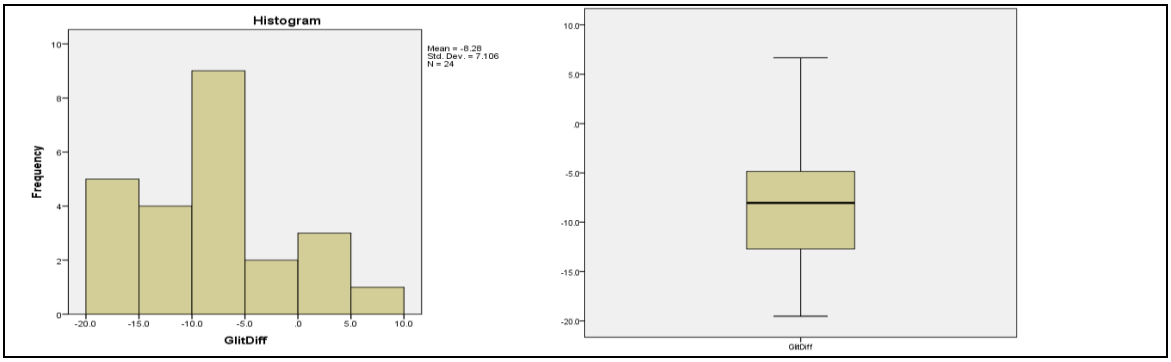


Table 39.8 Glitazones Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnova			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
GlitDiff	0.096	24	.200*	0.966	24	0.571

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 39.9 Glitazones Tests of Normality

Appendix 39 (Cont.)

Prescribing Data
Summary Statistics for Drugs used in Type 2 Diabetes

‘**Other Drugs’**

Descriptives				
			Statistic	Std. Error
OtherDiff	**Mean**		0.928	0.8398
	95% Confidence Interval for Mean	Lower Bound	-0.809	
		Upper Bound	2.666	
	5% Trimmed Mean		1.49	
	Median		1.755	
	Variance		16.928	
	Std. Deviation		4.1143	
	Minimum		-16.4	
	Maximum		5.8	
	Range		22.2	
	Interquartile Range		2.3	
	Skewness		-3.365	0.472
	Kurtosis		14.38	0.918

Table 39.10 Summary Statistics for ‘Other’ Drugs in T2DM

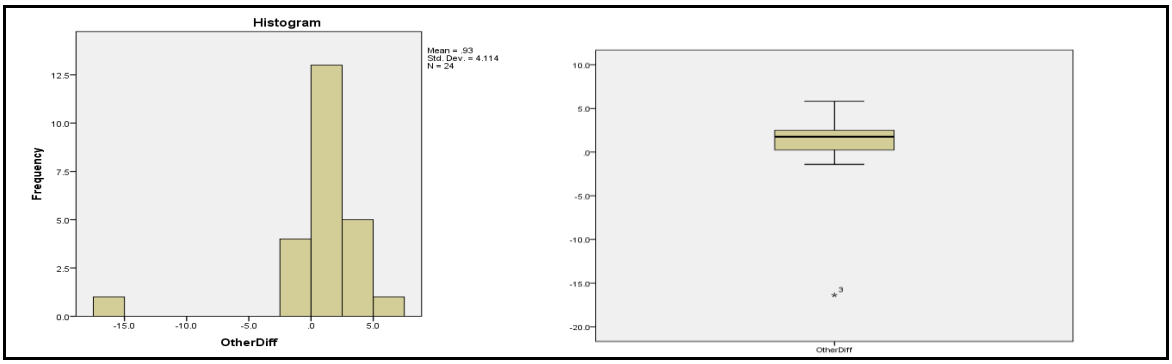


Table 39.11 ‘Other’ Drugs in T2DM Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
OtherDiff	0.243	24	0.001	0.644	24	0

a Lilliefors Significance Correction

Table 39.12 ‘Other’ Drugs in T2DM Tests of Normality

Appendix 40

Summary Statistics for Patient-Orientated Outcome Measures for Patients on NSAIDs

Patients on NSAIDs

Descriptives				
			Statistic	Std. Error
Overall NSAIDs	Mean		-0.011	0.0439
	95% Confidence Interval for Mean	Lower Bound	-0.103	
		Upper Bound	0.082	
	5% Trimmed Mean		-0.001	
	Median		0	
	Variance		0.037	
	Std. Deviation		0.1912	
	Minimum		-0.4	
	Maximum		0.2	
	Range		0.6	
	Interquartile Range		0.3	
	Skewness		-0.846	0.524
	Kurtosis		0.107	1.014

Table 40.1 Summary Statistics for NSAIDs

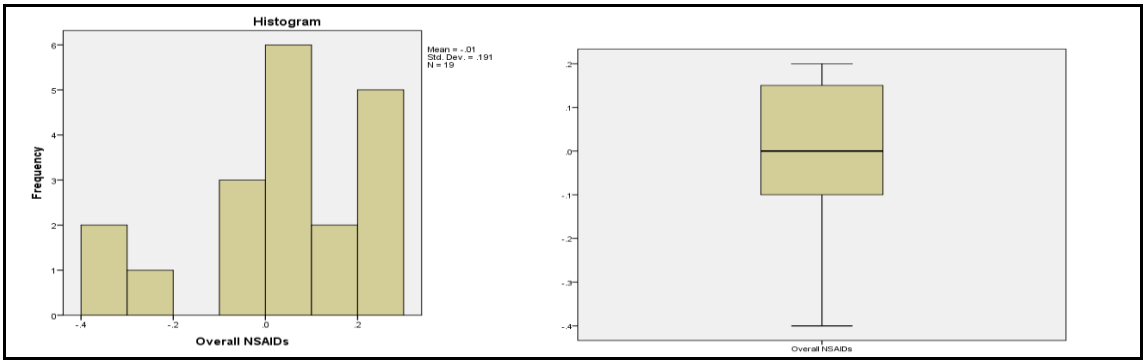


Table 40.2 NSAIDs Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Overall NSAIDs	0.206	19	0.033	0.869	19	0.014

a Lilliefors Significance Correction

Table 40.3 NSAIDs Tests of Normality

Appendix 40 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures for Patients on NSAIDs

Patients ≥ 65

Descriptives				
			Statistic	Std. Error
Over 65	Mean		-0.545	0.9721
	95% Confidence Interval for Mean	Lower Bound	-2.587	
		Upper Bound	1.498	
	5% Trimmed Mean		-0.589	
	Median		0.373	
	Variance		17.956	
	Std. Deviation		4.2375	
	Minimum		-8	
	Maximum		7.7	
	Range		15.7	
	Interquartile Range		6	
	Skewness		-0.131	0.524
	Kurtosis		-0.292	1.014

Table 40.4 Summary Statistics for Patients ≥ 65

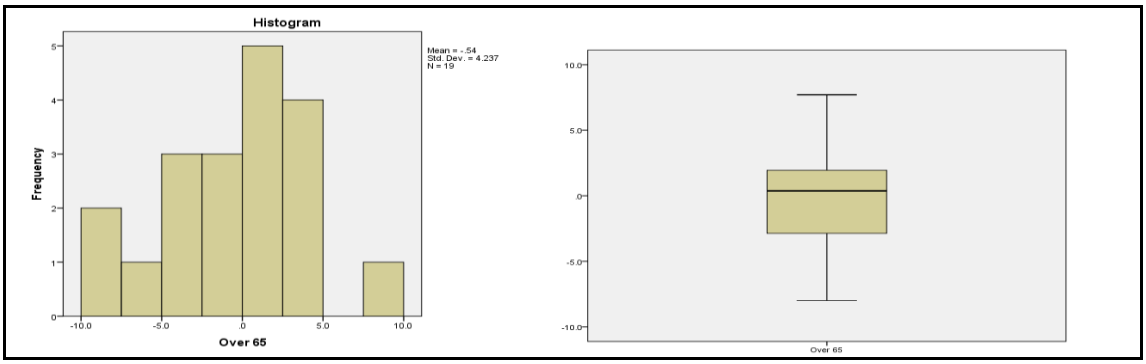


Table 40.5 Patients ≥ 65 Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Over 65	0.112	19	.200*	0.974	19	0.855

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 40.6 Patients ≥ 65 Tests of Normality

Appendix 40 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures for Patients on NSAIDs

Patients with Clinical (GI, CV or CKD) Risk Factor

Descriptives				
			Statistic	Std. Error
Total Risk	Mean		-0.647	0.8313
	95% Confidence Interval for Mean	Lower Bound	-2.394	
		Upper Bound	1.099	
	5% Trimmed Mean		-0.536	
	Median		0.1	
	Variance		13.129	
	Std. Deviation		3.6234	
	Minimum		-8.1	
	Maximum		4.8	
	Range		12.9	
	Interquartile Range		3.7	
	Skewness		-0.879	0.524
	Kurtosis		0.237	1.014

Table 40.7 Summary Statistics for Patients with Clinical Risk Factor

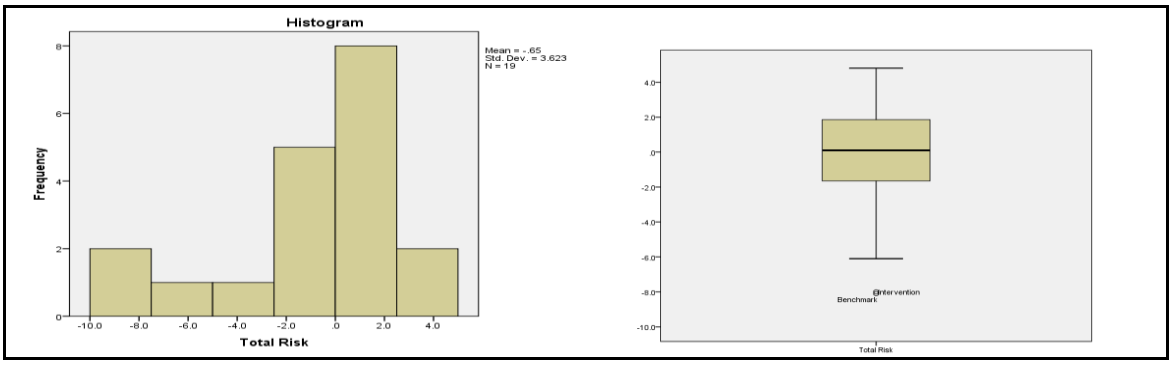


Table 40.8 Patients with Clinical Risk Factor Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Total Risk	0.175	19	0.127	0.916	19	0.095

a Lilliefors Significance Correction

Table 40.9 Patients with Clinical Risk Factor Tests of Normality

Appendix 40 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures for Patients on NSAIDs

Patients on Proton Pump Inhibitor

Descriptives				
			Statistic	Std. Error
Proportion on PPI	Mean		2.474	1.0149
	95% Confidence Interval for Mean	Lower Bound	0.342	
		Upper Bound	4.606	
	5% Trimmed Mean		2.332	
	Median		2	
	Variance		19.569	
	Std. Deviation		4.4237	
	Minimum		-6	
	Maximum		13.5	
	Range		19.5	
	Interquartile Range		5	
	Skewness		0.493	0.524
	Kurtosis		1.172	1.014

Table 40.10 Summary Statistics for Patients on PPI

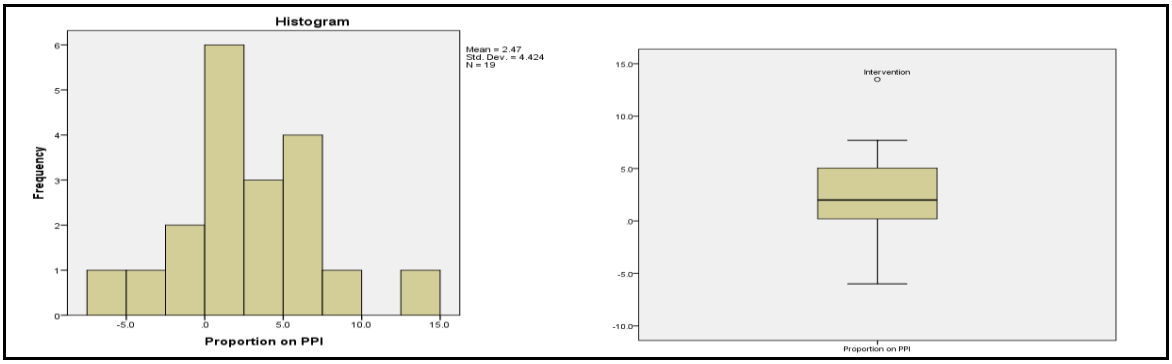


Table 40.11 Patients on PPI Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Proportion on PPI	0.124	19	.200*	0.964	19	0.655

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 40.12 Patients on PPI Tests of Normality

Appendix 40 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures for Patients on NSAIDs

Patients on Aspirin

Descriptives				
			Statistic	Std. Error
Proportion on Aspirin	Mean		-1.137	0.5805
	95% Confidence Interval for Mean	Lower Bound	-2.356	
		Upper Bound	0.083	
	5% Trimmed Mean		-1.102	
	Median		-1.4	
	Variance		6.402	
	Std. Deviation		2.5303	
	Minimum		-6.3	
	Maximum		3.4	
	Range		9.7	
	Interquartile Range		3.4	
	Skewness		-0.085	0.524
	Kurtosis		-0.258	1.014

Table 40.13 Summary Statistics for Patients on Aspirin

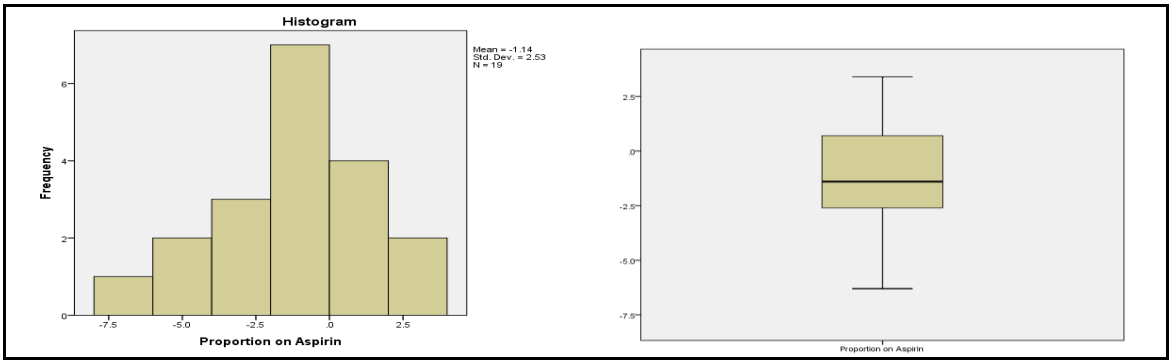


Table 40.14 Patients on Aspirin Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Proportion on PPI	0.124	19	.200*	0.964	19	0.655

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 40.15 Patients on Aspirin Tests of Normality

Appendix 40 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures for Patients on NSAIDs

Patients on SSRI

Descriptives				
			Statistic	Std. Error
Proportion on SSRI	Mean		1.037	0.5278
	95% Confidence Interval for Mean	Lower Bound	-0.072	
		Upper Bound	2.146	
	5% Trimmed Mean		1.063	
	Median		0.8	
	Variance		5.292	
	Std. Deviation		2.3005	
	Minimum		-3.1	
	Maximum		4.7	
	Range		7.8	
	Interquartile Range		2.9	
	Skewness		-0.088	0.524
	Kurtosis		-0.641	1.014

Table 40.16 Summary Statistics for Patients on SSRIs

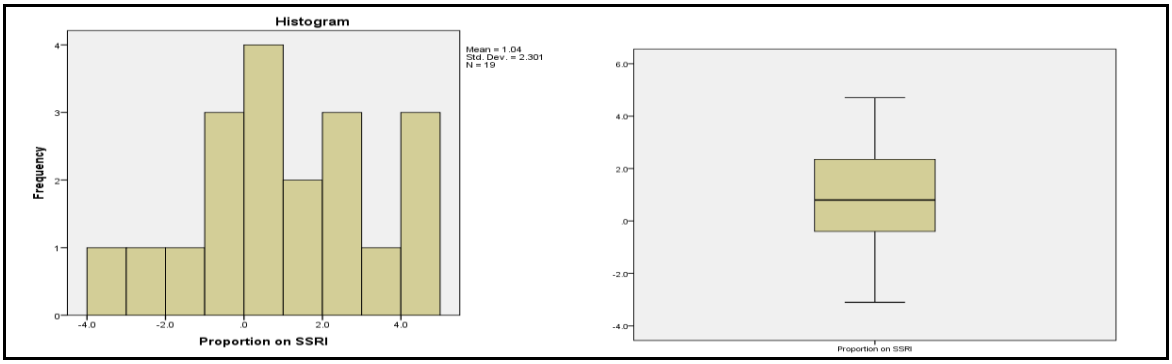


Table 40.17 Patients on SSRIs Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Proportion on SSRI	0.087	19	.200*	0.967	19	0.722

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 40.18 Patients on SSRIs Tests of Normality

Appendix 41

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes

Metformin

Descriptives				
			Statistic	Std. Error
Metformin Diff	Mean		0.135	0.7284
	95% Confidence Interval for Mean	Lower Bound	-1.395	
		Upper Bound	1.665	
	5% Trimmed Mean		0.269	
	Median		0.4	
	Variance		10.08	
	Std. Deviation		3.1749	
	Minimum		-8.2	
	Maximum		6.1	
	Range		14.3	
	Interquartile Range		3.8	
	Skewness		-0.917	0.524
	Kurtosis		1.948	1.014

Table 41.1 Summary Statistics for Metformin

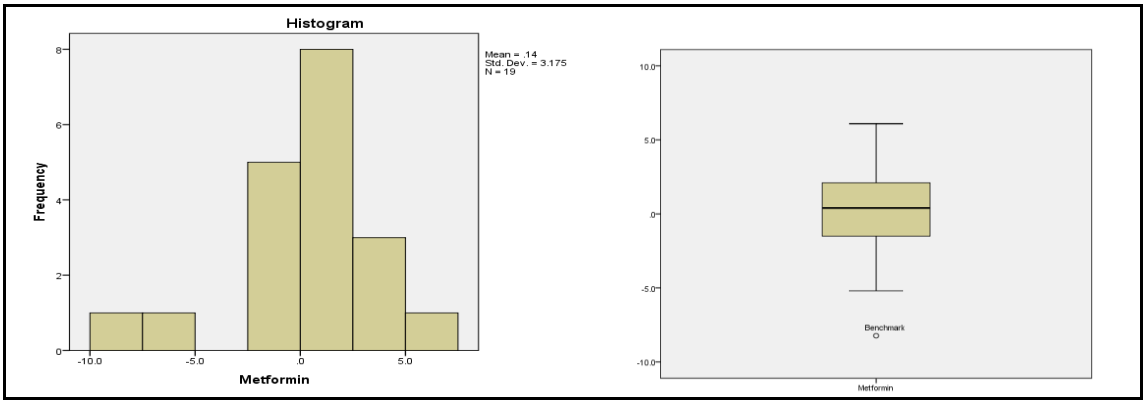


Table 41.2 Metformin Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Metformin Diff	0.145	19	.200*	0.934	19	0.208

Table 41.3 Metformin Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes

Renin-Angiotensin Drugs

Descriptives				
			Statistic	Std. Error
RAS-Diff	Mean		-0.437	0.4075
	95% Confidence Interval for Mean	Lower Bound	-1.293	
		Upper Bound	0.419	
	5% Trimmed Mean		-0.485	
	Median		-1.1	
	Variance		3.156	
	Std. Deviation		1.7765	
	Minimum		-3.8	
	Maximum		3.8	
	Range		7.6	
	Interquartile Range		2.2	
	Skewness		0.58	0.524
	Kurtosis		0.614	1.014

Table 41.4 Summary Statistics for Renin-Angiotensin Drugs

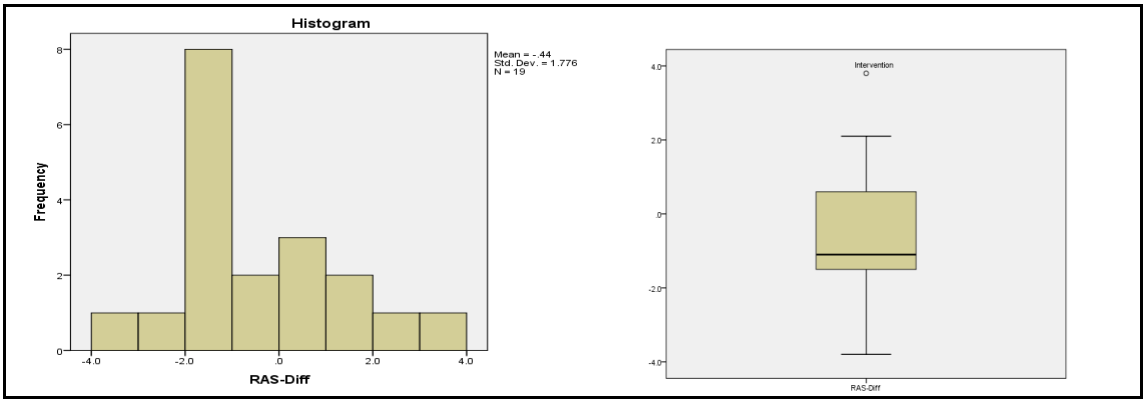


Table 41.5 Renin-Angiotensin Drugs Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
RAS-Diff	0.172	19	0.142	0.96	19	0.574

Table 41.6 Renin-Angiotensin Drugs Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes

ACE-Inhibitors (as Proportion of RAS Drugs)

Descriptives				
			Statistic	Std. Error
ACE-I Diff	Mean		0.163	0.5164
	95% Confidence Interval for Mean	Lower Bound	-0.922	
		Upper Bound	1.248	
	5% Trimmed Mean		0.242	
	Median		0.6	
	Variance		5.067	
	Std. Deviation		2.251	
	Minimum		-5.1	
	Maximum		4	
	Range		9.1	
	Interquartile Range		2.9	
	Skewness		-0.58	0.524
	Kurtosis		0.78	1.014

Table 41.7 Summary Statistics for ACE-Inhibitors as proportion of RAS Drugs

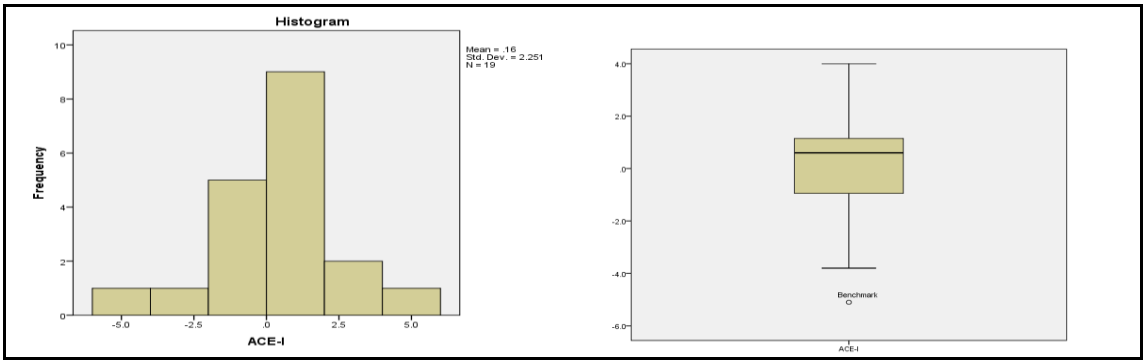


Table 41.8 ACE-Inhibitors as proportion of RAS Drugs Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
ACE-I	0.155	19	.200*	0.946	19	0.34

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 41.9 for ACE-Inhibitors as proportion of RAS Drugs Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes Lipid Lowering Agents

Descriptives				
			Statistic	Std. Error
LLA Diff	Mean		-1.042	0.7242
	95% Confidence Interval for Mean	Lower Bound	-2.564	
		Upper Bound	0.479	
	5% Trimmed Mean		-1.025	
	Median		-1.1	
	Variance		9.964	
	Std. Deviation		3.1565	
	Minimum		-8.2	
	Maximum		5.8	
	Range		14	
	Interquartile Range		3.8	
	Skewness		-0.066	0.524
	Kurtosis		0.94	1.014

Table 41.10 Summary Statistics for Lipid Lowering Agents

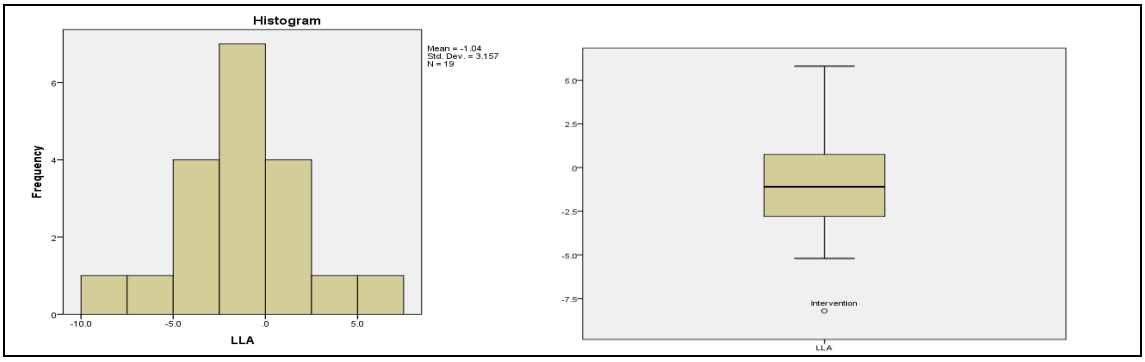


Table 41.11 Lipid Lowering Agents Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
LLA	0.12	19	.200*	0.986	19	0.988

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 41.12 Lipid Lowering Agents Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes Antiplatelets

Descriptives				
			Statistic	Std. Error
Aspirin Diff	Mean		-3.784	1.0295
	95% Confidence Interval for Mean	Lower Bound	-5.947	
		Upper Bound	-1.621	
	5% Trimmed Mean		-3.332	
	Median		-2.1	
	Variance		20.136	
	Std. Deviation		4.4873	
	Minimum		-16.6	
	Maximum		0.9	
	Range		17.5	
	Interquartile Range		5.8	
	Skewness		-1.607	0.524
	Kurtosis		2.734	1.014

Table 41.13 Summary Statistics for Aspirin (Antiplatelet)

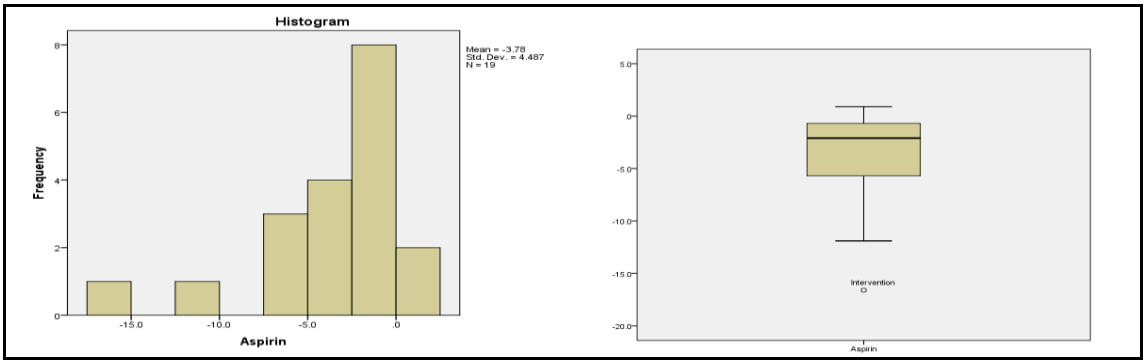


Table 41.14 Aspirin (Antiplatelet) Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Aspirin	0.173	19	0.139	0.841	19	0.005

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Table 41.15 Aspirin (Antiplatelet) Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient Outcome Measures in Type 2 Diabetes

Target Blood Pressure (140/80mmHg)

Descriptives				
			Statistic	Std. Error
BP Target Diff	Mean		0.137	1.2777
	95% Confidence Interval for Mean	Lower Bound	-2.548	
		Upper Bound	2.821	
	5% Trimmed Mean		0.058	
	Median		-1.1	
	Variance		31.02	
	Std. Deviation		5.5696	
	Minimum		-9.7	
	Maximum		11.4	
	Range		21.1	
	Interquartile Range		7.8	
	Skewness		0.312	0.524
	Kurtosis		-0.148	1.014

Table 41.16 Summary Statistics for Target Blood Pressure

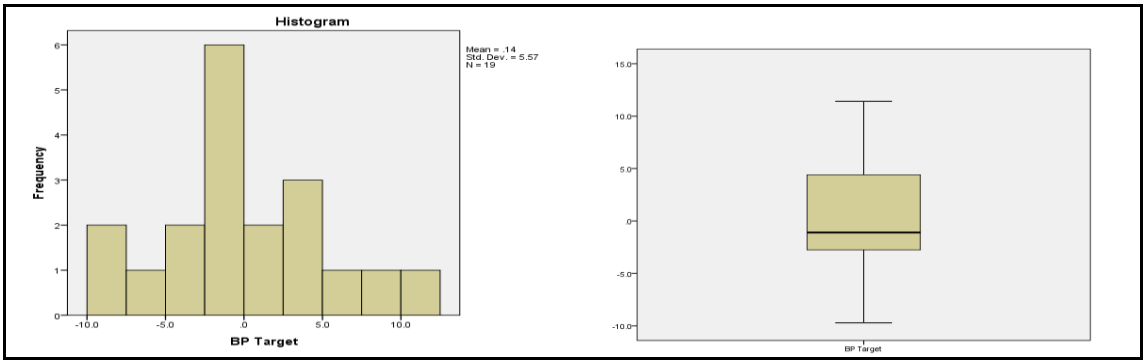

Table 41.17 Target Blood Pressure Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
BP Target	0.141	19	.200*	0.97	19	0.771

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 41.18 Target Blood Pressure Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient Outcome Measures in Type 2 Diabetes

Target Total Cholesterol (≤ 5mmol/l)

Descriptives				
			Statistic	Std. Error
Cholesterol Diff	Mean		1.506	0.7607
	95% Confidence Interval for Mean	Lower Bound	-0.107	
		Upper Bound	3.118	
	5% Trimmed Mean		1.44	
	Median		0.8	
	Variance		9.837	
	Std. Deviation		3.1364	
	Minimum		-2.8	
	Maximum		7	
	Range		9.8	
	Interquartile Range		5	
	Skewness		0.412	0.55
	Kurtosis		-1.015	1.063

Table 41.19 Summary Statistics for Target Total Cholesterol

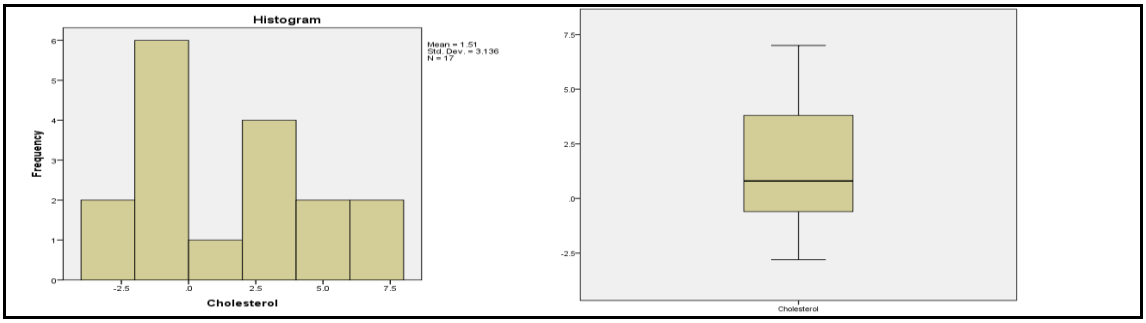

Table 41.20 Target Total Cholesterol Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Cholesterol	0.177	17	0.16	0.939	17	0.303

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Table 41.21 Target Total Cholesterol Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient Outcome Measures in Type 2 Diabetes

Target HbA1c (≤ 7.5%)

Descriptives				
			Statistic	Std. Error
HbA1c (7.5%)Diff	Mean		-1.421	0.917
	95% Confidence Interval for Mean	Lower Bound	-3.348	
		Upper Bound	0.506	
	5% Trimmed Mean		-1.368	
	Median		-2	
	Variance		15.978	
	Std. Deviation		3.9973	
	Minimum		-9.3	
	Maximum		5.5	
	Range		14.8	
	Interquartile Range		6.6	
	Skewness		0.051	0.524
	Kurtosis		-0.505	1.014

Table 41.22 Summary Statistics for Target HbA1c (≤ 7.5%)

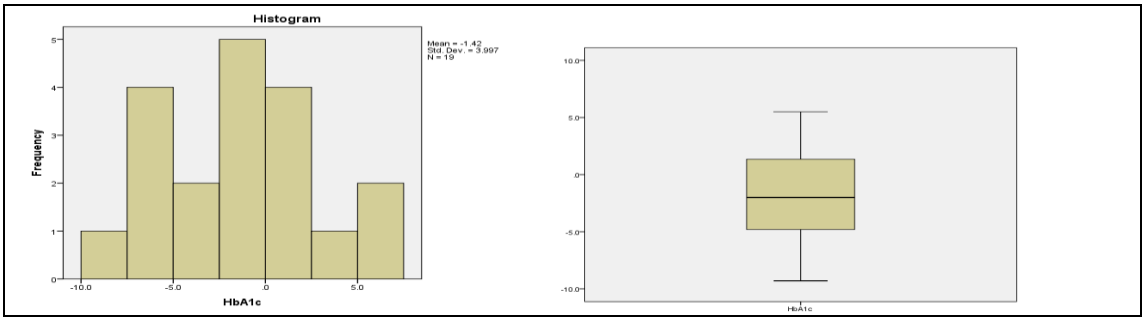

Table 41.23 Target HbA1c (≤ 7.5%) Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnova			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
HbA1c (7.5%)	0.112	19	.200*	0.967	19	0.722

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 41.24 Target HbA1c (≤ 7.5%) Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient Outcome Measures in Type 2 Diabetes

Target HbA1c (≤ 7.5%)

Descriptives				
			Statistic	Std. Error
HbA1c (9.0%) Diff	Mean		-1.432	0.9313
	95% Confidence Interval for Mean	Lower Bound	-3.388	
		Upper Bound	0.525	
	5% Trimmed Mean		-1.335	
	Median		-0.6	
	Variance		16.479	
	Std. Deviation		4.0594	
	Minimum		-10.3	
	Maximum		5.7	
	Range		16	
	Interquartile Range		3.4	
	Skewness		-0.812	0.524
	Kurtosis		1.057	1.014

Table 41.25 Summary Statistics for Target HbA1c (≤ 9.0%)

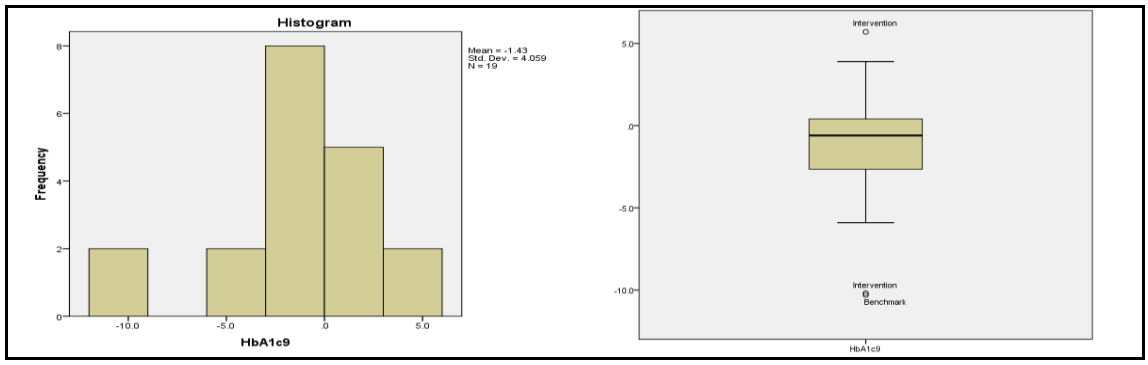

Table 41.26 Target HbA1c (≤ 9.0%) Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
HbA1c9	0.148	19	.200*	0.923	19	0.129

* This is a lower bound of the true significance.

a Lilliefors Significance Correction

Table 41.27 Target HbA1c (≤ 9.0%) Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes

ACR Measured

Descriptives				
			Statistic	Std. Error
ACR Measured Diff	Mean		2.974	1.926
	95% Confidence Interval for Mean	Lower Bound	-1.073	
		Upper Bound	7.02	
	5% Trimmed Mean		1.615	
	Median		0.6	
	Variance		70.48	
	Std. Deviation		8.3952	
	Minimum		-5	
	Maximum		35.4	
	Range		40.4	
	Interquartile Range		6.1	
	Skewness		3.491	0.524
	Kurtosis		13.794	1.014

Table 41.28 Summary Statistics for ACR Measured

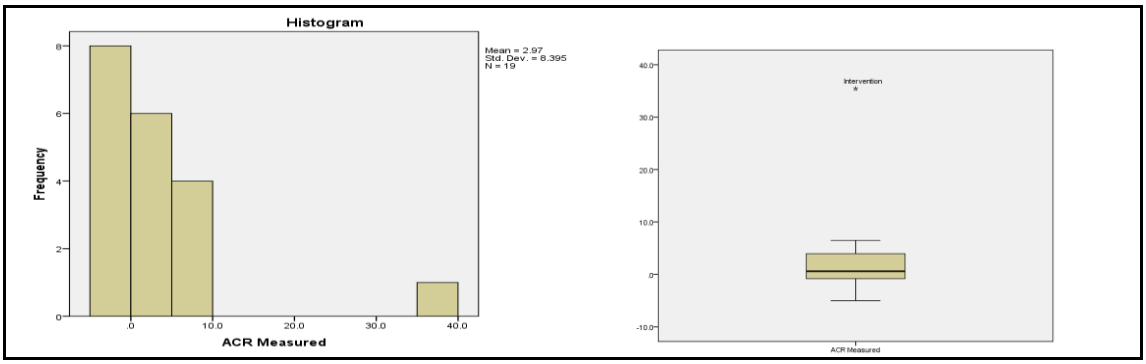

Table 41.29 ACR Measured Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
ACR Measured	0.285	19	0	0.57	19	0

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Table 41.30 ACR Measured Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes

Microalbuminuria Recorded

Descriptives				
			Statistic	Std. Error
Microalbuminuria Detected (Diff)	Mean		0.253	0.6454
	95% Confidence Interval for Mean	Lower Bound	-1.103	
		Upper Bound	1.609	
	5% Trimmed Mean		0.142	
	Median		-0.4	
	Variance		7.915	
	Std. Deviation		2.8133	
	Minimum		-5.4	
	Maximum		7.9	
	Range		13.3	
	Interquartile Range		2.9	
	Skewness		0.846	0.524
	Kurtosis		2.352	1.014

Table 41.31 Summary Statistics for Microalbuminuria Recorded

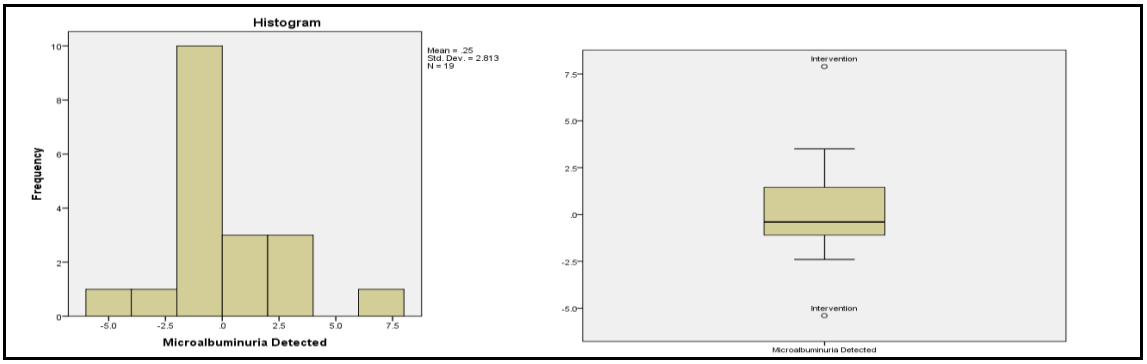

Table 41.32 Microalbuminuria Recorded Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Microalbuminuria Detected	0.195	19	0.054	0.927	19	0.15

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Table 41.33 Microalbuminuria Recorded Tests of Normality

Appendix 41 (Cont.)

Summary Statistics for Patient-Orientated Outcome Measures in Type 2 Diabetes Microalbuminuria on RAS Drug

Descriptives				
			Statistic	Std. Error
m/aRASDiff	Mean		3.842	3.6084
	95% Confidence Interval for Mean	Lower Bound	-3.739	
		Upper Bound	11.423	
	5% Trimmed Mean		2.658	
	Median		0.2	
	Variance		247.388	
	Std. Deviation		15.7286	
	Minimum		-18.1	
	Maximum		47.1	
	Range		65.2	
	Interquartile Range		12	
	Skewness		1.489	0.524
	Kurtosis		2.549	1.014

Table 41.34 Summary Statistics for Microalbuminuria on RAS Drug

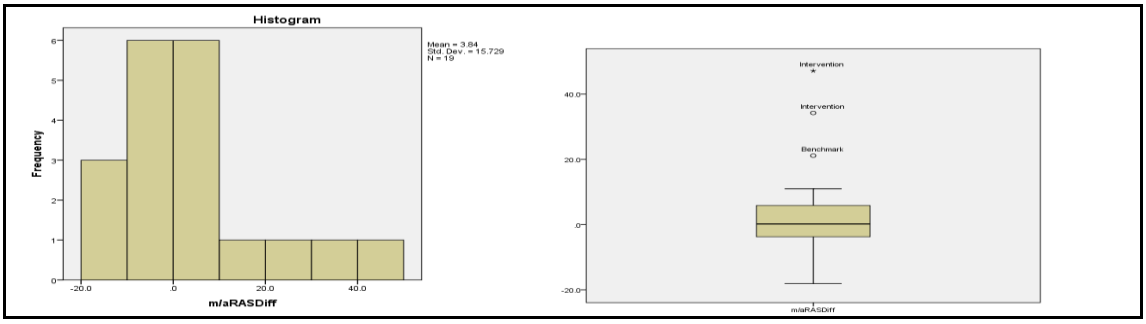

Table 41.35 Microalbuminuria on RAS Drug Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
m/aRASDiff	0.217	19	0.019	0.86	19	0.01

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Table 41.36 Microalbuminuria on RAS Drug Tests of Normality

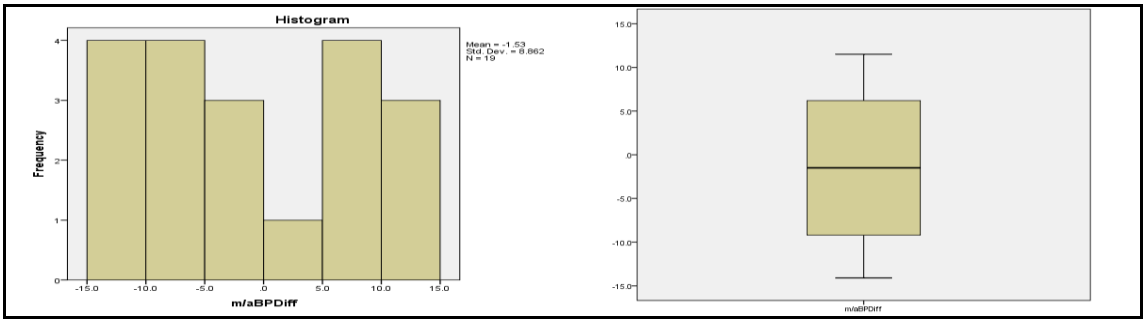
Appendix 41 (Cont.)

Summary Statistics for Patient Outcome Measures in Type 2 Diabetes

Microalbuminuria BP Target Achieved

Descriptives				
			Statistic	Std. Error
m/a BP Diff	Mean		-1.526	2.033
	95% Confidence Interval for Mean	Lower Bound	-5.798	
		Upper Bound	2.745	
	5% Trimmed Mean		-1.551	
	Median		-1.5	
	Variance		78.531	
	Std. Deviation		8.8618	
	Minimum		-14.1	
	Maximum		11.5	
	Range		25.6	
	Interquartile Range		15.5	
	Skewness		-0.03	0.524
	Kurtosis		-1.478	1.014

Table 41.37 Summary Statistics for Microalbuminuria BP Target Achieved



41.38 Microalbuminuria BP Target Achieved Histogram and Box Plot

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
m/aBPDiff	0.174	19	0.134	0.917	19	0.1

a Lilliefors Significance Correction

Table 41.39 Microalbuminuria BP Target Achieved Tests of Normality

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